Product Monograph

Including Patient Medication Information

[Pr]Taro-Diclofenac Potassium Powder for Oral Solution

Diclofenac Potassium For Oral Solution USP

For Oral use

50 mg of diclofenac potassium

Nonsteroidal Anti-Inflammatory Drug (NSAID)

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Recent Major Label Changes
Not applicable

Table of Contents
Certain sections or subsections that are not applicable at the time of the preparation of the most recent authorized product monograph are not listed.

Table of Contents

Part 1: Healthcare Professional Information

1. Indications

Adults
Taro-Diclofenac Potassium Powder for Oral Solution (diclofenac potassium) is indicated for the acute treatment of migraine attacks with or without aura in adults 18 years and older.

Efficacy and safety of Taro-Diclofenac Potassium Powder for Oral Solution beyond a single dose have not been studied.

Taro-Diclofenac Potassium Powder for Oral Solution is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic, basilar, or ophthalmoplegic migraine. Safety and efficacy have not been established for cluster headache which is present in an older, predominantly male population.

Throughout this document, the term NSAIDs refers to both non-selective NSAIDs and selective COX-2 inhibitor NSAIDs, unless otherwise indicated.

For patients with an increased risk of developing Cardiovascular (CV) and/or Gastrointestinal (GI) adverse events, other management strategies that do NOT include the use of NSAIDs should be considered first (See 2 Contraindications and 7 Warnings and Precautions, Cardiovascular; Gastrointestinal).

Use of Taro-Diclofenac Potassium Powder for Oral Solution should be limited to a single dose and for the fewest number of days per month as needed, in order to minimize the potential risk for cardiovascular or gastrointestinal adverse events (See 2 Contraindications and 7 Warnings and Precautions, Cardiovascular; Gastrointestinal).

1.1 Pediatrics (< 18 years of age):
Safety and efficacy of diclofenac potassium powder for oral solution has not been studied in patients below the age of 18 years, and its use in this population is contraindicated (See 2 Contraindications).

1.2 Geriatrics (> 65 years of age):
Evidence from clinical studies and post-market experience suggests that use in the geriatric population is associated with differences in safety (see 4.2 Recommended Dose and Dosage Adjustment and 7.1.4 Geriatrics).

2. Contraindications

Taro-Diclofenac Potassium Powder for Oral Solution is contraindicated:

- In patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see 6 Dosage Forms, Strengths, Composition, and Packaging.
- In the perioperative pain setting of Coronary Artery Bypass Graft (CABG) surgery. Although Taro-Diclofenac Potassium Powder for Oral Solution has NOT been studied in this patient population, a selective COX-2 inhibitor NSAID studied in such a setting has led to an increased incidence of cardiovascular/thromboembolic events, deep surgical infections and sternal wound complications.
- During the third trimester of pregnancy, because of risk of premature closure of the ductus arteriosus and prolonged parturition.

- In women who are breastfeeding, because of the potential for serious adverse reactions in nursing infants.
- In patients with severe uncontrolled heart failure.
- In patients with a history of asthma, urticaria, or allergic-type reactions after taking ASA or other NSAIDs (i.e. complete or partial syndrome of ASA-intolerance - rhinosinusitis, urticaria/ angioedema, nasal polyps, asthma). Fatal anaphylactoid reactions have occurred in such individuals after taking NSAIDs. Individuals with the above medical problems are at risk of a severe reaction even if they have taken NSAIDs in the past without any adverse reaction. The potential for cross-reactivity between different NSAIDs must be kept in mind (see 7 Warnings and Precautions, Sensitivity/Resistance; Anaphylactoid Reactions).
- In patients with active gastric / duodenal / peptic ulcer, active GI bleeding.
- In patients with cerebrovascular bleeding or other bleeding disorders.
- In patients with inflammatory bowel disease.
- In patients with severe liver impairment or active liver disease.
- In patients with severe renal impairment (creatinine clearance <30 mL/min or 0.5 mL/sec) or deteriorating renal disease (individuals with lesser degrees of renal impairment are at risk of deterioration of their renal function when prescribed NSAIDs and must be monitored) (see 7 Warnings and Precautions, Renal).
- In patients with known hyperkalemia (see 7 Warnings and Precautions, Renal, Fluid and Electrolyte Balance).
- In children and adolescents less than 18 years of age**.**

3. Serious Warnings and Precautions Box

Serious Warnings and Precautions

Risk of Cardiovascular Adverse Events:
Diclofenac is associated with an increased risk of cardiovascular adverse events (such as myocardial infarction, stroke or thrombotic events) that is comparable to COX-2 inhibitors and which can be fatal (see 7 Warnings and Precautions, Cardiovascular). The risk may increase with duration of use. Meta-analyses of randomized clinical trials comparing several different NSAIDs suggest that diclofenac, particularly at higher doses, is associated with an increased risk of cardiovascular adverse events that is comparable to COX-2 inhibitors. Large population-based observational studies conducted in the general population also support these findings.

Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk. To minimize the potential risk for an adverse CV event, Taro-Diclofenac Potassium Powder for Oral Solution should be used for the fewest number of days per month as needed, based on individual treatment goals.

Treatment with Taro-Diclofenac Potassium Powder for Oral Solution is not recommended in patients with pre-existing cardiovascular disease (congestive heart failure NYHA II-IV, ischemic heart disease, peripheral arterial disease), cerebrovascular disease, uncontrolled hypertension, and caution should be exercised in patients with risk factors for cardiovascular disease (e.g. hypertension, hyperlipidemia, diabetes mellitus and smoking). These patients should be treated with Taro-Diclofenac Potassium Powder for Oral Solution only after careful consideration.

Use of NSAIDs, such as Taro-Diclofenac Potassium Powder for Oral Solution can promote sodium retention in a dose dependent manner, through a renal mechanism, which can result in increased blood pressure and/or exacerbation of congestive heart failure (see 7 Warnings and Precautions, Renal, Fluid and Electrolyte Balance).

Risk of Gastrointestinal (GI) Adverse Events:
Use of NSAIDs, such as Taro-Diclofenac Potassium Powder for Oral Solution is associated with an increased incidence of gastrointestinal adverse events (such as peptic/duodenal ulceration, perforation, obstruction and gastrointestinal bleeding) which can be fatal (see 7 Warnings and Precautions, Gastrointestinal). Elderly patients are at a greater risk.

Risk in Pregnancy:

Caution should be exercised in prescribing Taro-Diclofenac Potassium Powder for Oral Solution during the first and second trimesters of pregnancy. Use of NSAIDS at approximately 20 weeks of gestation or later may cause fetal renal dysfunction leading to oligohydramnios and neonatal renal impairment or failure (see 7.1.1 Pregnancy). Taro-Diclofenac Potassium Powder for Oral Solution is contraindicated for use during the third trimester because of risk of premature closure of the ductus arteriosus and uterine inertia (prolonged parturition) (see 2 Contraindications).

4. Dosage and Administration

4.1 Dosing Considerations

- Taro-Diclofenac Potassium Powder for Oral Solution is recommended only for the acute treatment of migraine attacks. Taro-Diclofenac Potassium Powder for Oral Solution should not be used prophylactically.
- Controlled trials have not studied a second dose if the initial dose is ineffective. The safety of treating more than one headache in a 30-day period has not been studied.

4.2 Recommended Dose and Dosage Adjustment

- Only one single dose sachet of Taro-Diclofenac Potassium Powder for Oral Solution is to be taken for the acute treatment of a migraine attack. The safety and efficacy of a second dose have not been studied.
- **Pregnancy:** Taro-Diclofenac Potassium Powder for Oral Solution is contraindicated for use during the third trimester of pregnancy. Taro-Diclofenac Potassium Powder for Oral Solution should not be prescribed during the first and second trimesters of pregnancy, unless the potential benefit to the mother outweighs the potential risk to the fetus (see 7.1.1 Pregnancy).
- **Pediatrics:** Taro-Diclofenac Potassium Powder for Oral Solution is contraindicated in pediatric patients below the age of 18 years.
- **Geriatrics:** Care should be taken when using Taro-Diclofenac Potassium Powder for Oral Solution in the elderly, frail and debilitated. Elderly patients are at increased risk for serious GI adverse events and are more likely to have decreased renal function (see 7.1.4 Geriatrics).
- **Renal Impairment:** Taro-Diclofenac Potassium Powder for Oral Solution is not recommended in patients with renal impairment (see 10.3 Pharmacokinetics, Special populations and conditions, Renal Insufficiency) and is contraindicated in patients with severe renal impairment (see 2 Contraindications and 7 Warnings and Precautions, Renal).
- **Hepatic Impairment:** Taro-Diclofenac Potassium Powder for Oral Solution is not recommended in patients with hepatic impairment (See 10.3 Pharmacokinetics, Special populations and conditions, Hepatic Insufficiency) and is contraindicated in patients with severe hepatic impairment function (see 2 Contraindications and 7 Warnings and Precautions, Hepatic/ Biliary/ Pancreatic).
- **Migraine symptoms:** Caution is recommended when prescribing Taro-Diclofenac Potassium Powder for Oral Solution when vomiting is a significant component of the migraine attack.

4.4. Administration

Diclofenac potassium powder for oral solution:

Empty the contents of one individual dose sachet into a cup containing 30 to 60 mL (1 to 2 ounce) of water; mix well. Ensure that the powder is completely dissolved before drinking. Drink the water-powder mixture immediately after re-constitution. Do NOT use liquids other than water.

Taking Taro-Diclofenac Potassium Powder for Oral Solution with a meal may cause a delay in efficacy (see 9.5 Drug-Food Interactions).

5. Overdose

Symptoms following acute diclofenac overdose are usually limited to lethargy, drowsiness, dizziness, tinnitus or convulsions, nausea, vomiting, epigastric pain and diarrhea, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Hypertension, acute renal failure, respiratory depression and coma may occur, but are rare. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAIDs, and may occur following an overdose.

Therapeutic measures

Management of acute poisoning with NSAIDs, including diclofenac potassium, essentially consists of supportive measures and symptomatic treatment. Supportive measures and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastrointestinal disorder, and respiratory depression. Special measures such as forced diuresis, dialysis or haemoperfusion are probably of no help in eliminating NSAIDs, including diclofenac potassium, due to the high protein binding and extensive metabolism. Activated charcoal may be considered after ingestion of a potentially toxic overdose, and gastric decontamination (e.g. vomiting, gastric lavage) after ingestion of a potentially life - threatening overdose.

For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669).

6. Dosage Forms, Strengths, Composition, and Packaging

Table 1 – Dosage Forms, Strengths, and Composition

Route of Administration	Dosage Form/ Strength/Composition	Non-Medicinal Ingredients
oral	Powder for oral solution / 50 mg	Aspartame (equivalent to 25 mg phenylalanine), glyceryl dibehenate, mannitol, modified food starch, Natural & Artificial peppermint flavour, monoammonium glycyrrhizinate, potassium bicarbonate and saccharin sodium.

Description:

Taro-Diclofenac Potassium Powder for Oral Solution 50 mg (diclofenac potassium powder for oral solution) is supplied as one or more sets of three perforated co-joined individual dose sachets. Each individual dose sachet is designed to deliver a dose of 50 mg diclofenac potassium when mixed in water.

Taro-Diclofenac Potassium Powder for Oral Solution is a white to off-white powder for Oral Solution packaged in individual dose aluminum sachets.

Boxes of three (3) Taro-Diclofenac Potassium Powder for Oral Solution Individual dose Sachets Boxes of nine (9) Taro-Diclofenac Potassium Powder for Oral Solution Individual dose Sachets

7. Warnings and Precautions

See 3 Serious Warnings and Precautions Box.

General

Frail or debilitated patients may tolerate side effects less well and therefore special care should be taken in treating this population. **To minimize the potential risk for an adverse event, use of Taro-Diclofenac Potassium Powder for Oral Solution should be limited to a single dose and the fewest number of days per month as needed.** As with other NSAIDs, caution should be used in the treatment of elderly patients who are more likely to be suffering from impaired renal, hepatic or cardiac function. For high risk patients, alternate therapies that do not involve NSAIDs should be considered.
Concomitant use of NSAIDs: Taro-Diclofenac Potassium Powder for Oral Solution is NOT recommended for use with other NSAIDs, with the exception of low-dose ASA for cardiovascular prophylaxis, because of the absence of any evidence demonstrating synergistic benefits and the potential for additive adverse

reactions (see 9.4 Drug-/Drug Interactions, - Acetylsalicylic acid (ASA) or other NSAIDs).
Taro-Diclofenac Potassium Powder for Oral Solution should not be used concomitantly with diclofenac sodium containing products (e.g. VOLTAREN*) since both exist in plasma as the same active organic anion.
Interchangeability with Other Formulations of Diclofenac: Different formulations of diclofenac (e.g. diclofenac sodium or diclofenac potassium) may not be bioequivalent even if the milligram strength is the same. Taro-Diclofenac Potassium Powder for Oral Solution cannot be replaced by any other diclofenac formulations, nor is it possible to convert dosing from any other formulation of diclofenac to Taro-Diclofenac Potassium Powder for Oral Solution.
Phenylketonurics: Phenylketonurics patients should be informed that Taro-Diclofenac Potassium Powder for Oral Solution contains aspartame equivalent to 25 mg phenylalanine per packet.

Carcinogenesis and Genotoxicity
See 16 Non-Clinical Toxicology.

Cardiovascular
Diclofenac is associated with an increased incidence of cardiovascular (CV) adverse events (such as myocardial infarction, stroke or thrombotic events) similar to COX-2 inhibitors which can be fatal. The risk may increase with the dose and duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.
It should be noted that patients with migraine may be at increased risk of certain cerebrovascular events (e.g., stroke, hemorrhage, transient ischemic attack).

Caution should be exercised in prescribing Taro-Diclofenac Potassium Powder for Oral Solution to patients with risk factors for cardiovascular disease, cerebrovascular disease or renal disease, including but not limited to:

- **Hypertension**
- **Dyslipidemia / Hyperlipidemia**
- **Diabetes Mellitus**
- **Congestive Heart Failure (NYHA I)**
- **Coronary Artery Disease (Atherosclerosis)**
- **Peripheral Arterial Disease**
- **Smoking**
- **Creatinine Clearance < 60 mL/min or 1 mL/sec**

Use of NSAIDs, such as diclofenac potassium, can lead to new hypertension or can worsen pre-existing hypertension, either of which may increase the risk of cardiovascular events as described above. Thus, blood pressure should be monitored regularly. Consideration should be given to discontinuing diclofenac potassium powder for oral solution should hypertension either develop or worsen with its use.
Use of NSAIDs, such as Taro-Diclofenac Potassium Powder for Oral Solution , can induce fluid retention and edema, and may exacerbate congestive heart failure through a renally-mediated mechanism (see 7 Warnings and Precautions, Renal Fluid and Electrolyte Balance).

For patients with a high risk of developing an adverse CV event, other management strategies that do NOT include the use of NSAIDs should be considered first. **To minimize the potential risk for an adverse CV event, Taro-Diclofenac Potassium Powder for Oral Solution use should be limited to a single dose, and the fewest number of days per month as needed.**

Driving and Operating Machinery
Patients experiencing visual disturbances, dizziness, vertigo, somnolence or other central nervous system disturbances while taking Taro-Diclofenac Potassium Powder for Oral Solution should refrain from driving or using machines (see 8 Adverse Reactions).

Endocrine and Metabolism

Corticosteroids: Diclofenac potassium is NOT a substitute for corticosteroids. It does NOT treat corticosteroid insufficiency. Abrupt discontinuation of corticosteroids may lead to exacerbation of corticosteroid- responsive illness. Patients on prolonged corticosteroid therapy should have their therapy tapered slowly if a decision is made to discontinue corticosteroids (see 9.4 Drug-Drug Interactions, Glucocorticoids).

Gastrointestinal

Serious GI toxicity (sometimes fatal), such as peptic / duodenal ulceration, inflammation, perforation, obstruction and gastrointestinal bleeding, can occur at any time, with or without warning symptoms, in patients treated with NSAIDs, such as diclofenac potassium. Minor upper GI problems, such as dyspepsia, commonly occur at any time. Healthcare professionals should remain alert for ulceration and bleeding in patients treated with diclofenac potassium powder for oral solution, even in the absence of previous GI tract symptoms. Most spontaneous reports of fatal GI events are in elderly or debilitated patients and therefore special care should be taken in treating this population. To minimize the potential risk for an adverse GI event, Taro-Diclofenac Potassium Powder for Oral Solution use should be limited to a single dose, and the fewest number of days per month as needed, based on individual treatment goals. For high risk patients, alternate therapies that do not involve NSAIDs should be considered (see 7.1.4 Geriatrics). Patients should be informed about the signs and/or symptoms of serious GI toxicity and instructed to discontinue using Taro-Diclofenac Potassium Powder for Oral Solution and seek emergency medical attention if they experience any such symptoms. The utility of periodic laboratory monitoring has NOT been demonstrated, nor has it been adequately assessed. Most patients who develop a serious upper GI adverse event on NSAID therapy have no symptoms. Upper GI ulcers, gross bleeding or perforation, caused by NSAIDs, appear to occur in approximately 1% of patients treated for 3 to 6 months, and in about 2 to 4% of patients treated for one year. These trends continue, thus increasing the likelihood of developing a serious GI event at some time during the course of therapy. Even short-term therapy has its risks. Caution should be taken if prescribing Taro-Diclofenac Potassium Powder for Oral Solution to patients with a prior history of peptic / duodenal ulcer disease or gastrointestinal bleeding as these individuals have a greater than 10-fold higher risk for developing a GI bleed when taking a NSAID than patients with neither of these risk factors. Other risk factors for GI ulceration and bleeding include the following: *Helicobacter pylori* infection, increased age, prolonged use of NSAID therapy, excess alcohol intake, smoking, poor general health status or concomitant therapy with any of the following:

- Anti-coagulants (e.g. warfarin)
- Anti-platelet agents (e.g. ASA, clopidogrel)
- Oral corticosteroids (e.g. prednisone)
- Selective Serotonin Reuptake Inhibitors (SSRIs) (e.g. citalopram, fluoxetine, paroxetine, sertraline)

Genitourinary

Some NSAIDs are associated with persistent urinary symptoms (bladder pain, dysuria, and urinary frequency), hematuria or cystitis. The onset of these symptoms may occur at any time after the initiation of therapy with a NSAID. Should urinary symptoms occur, in the absence of an alternate explanation, treatment with Taro-Diclofenac Potassium Powder for Oral Solution should be stopped to ascertain if symptoms disappear. This should be done before urological investigations or treatments are carried out.

Hematologic

NSAIDs inhibiting prostaglandin biosynthesis interfere with platelet function to varying degrees; patients who may be adversely affected by such an action, such as those on anti-coagulants or suffering from hemophilia or platelet disorders should be carefully observed when Taro-Diclofenac Potassium Powder for Oral Solution is administered.

Anti-coagulants: Numerous studies have shown that the concomitant use of NSAIDs and anti-coagulants

increases the risk of bleeding. Concurrent therapy of Taro-Diclofenac Potassium Powder for Oral Solution with warfarin requires close monitoring of the international normalized ratio (INR).

Even with therapeutic INR monitoring, increased bleeding may occur.

Anti-platelet Effects: NSAIDs inhibit platelet aggregation and have been shown to prolong bleeding time in some patients. Unlike acetylsalicylic acid (ASA), their effect on platelet function is quantitatively less, or of shorter duration, and is reversible.

Taro-Diclofenac Potassium Powder for Oral Solution and other NSAIDs have no proven efficacy as anti-platelet agents and should NOT be used as a substitute for ASA or other anti-platelet agents for prophylaxis of cardiovascular thromboembolic diseases. Anti-platelet therapies (e.g. ASA) should NOT be discontinued. There is some evidence that use of NSAIDs with ASA can markedly attenuate the cardioprotective effects of ASA (see 9.4 Drug-Drug Interactions, - Acetylsalicylic Acid (ASA) or other NSAIDs).

Concomitant administration of Taro-Diclofenac Potassium Powder for Oral Solution with low dose ASA increases the risk of GI ulceration and associated complications.

Blood dyscrasias: Blood dyscrasias (such as neutropenia, leukopenia, thrombocytopenia, aplastic anemia and agranulocytosis) associated with the use of NSAIDs are rare, but could occur with severe consequences.

Anemia is sometimes seen in patients receiving NSAIDs, including Taro-Diclofenac Potassium Powder for Oral Solution. This may be due to fluid retention, GI blood loss, or an incompletely described effect upon erythropoiesis. Patients on long-term treatment with NSAIDs, including Taro-Diclofenac Potassium Powder for Oral Solution, should have their hemoglobin or hematocrit checked if they exhibit any signs or symptoms of anemia or blood loss.

Hepatic/Biliary/Pancreatic

As with other NSAIDs including Taro-Diclofenac Potassium Powder for Oral Solution, borderline elevations of one or more liver enzyme tests (AST, ALT, alkaline phosphatase) may occur in up to 15% of patients. These abnormalities may progress, may remain essentially unchanged, or may be transient with continued therapy.

In clinical trials with diclofenac containing product, meaningful elevations (i.e., more than 3 × upper limit of normal (ULN)) of AST occurred in about 2% of approximately 5,700 patients at some time during treatment (ALT was not measured in all studies). In an open-label, controlled trial of 3,700 patients treated for 2–6 months with diclofenac containing product, patients were monitored at 8 weeks and 1,200 patients were monitored again at 24 weeks. Meaningful elevations of ALT and/or AST occurred in about 4% of the 3,700 patients and included marked elevations (>8 × ULN) in about 1% of the 3,700 patients. In this open-label study, a higher incidence of borderline (< 3 × ULN), moderate (3–8 × ULN), and marked (>8 × ULN) elevations of ALT or AST was observed in patients receiving diclofenac when compared to other NSAIDs. Almost all clinically relevant elevations in transaminases were detected before patients became symptomatic.

Post-market cases of drug-induced hepatotoxicity have been reported in the first month, and in some cases the first 2 months of diclofenac therapy, but can occur at any time during treatment with diclofenac. Post-marketing surveillance has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. Some of these reported cases resulted in fatalities or liver transplantation.

A patient with symptoms and/or signs suggesting liver dysfunction, or in whom an abnormal liver function test has occurred, should be evaluated for evidence of the development of a more severe hepatic reaction while on therapy with this drug.

To minimize the possibility that hepatic injury will become severe between transaminase measurements,

physicians should inform patients of the warning signs and symptoms of hepatotoxicity and the appropriate action patients should take if these signs and symptoms appear. Physicians should exercise caution when prescribing Taro-Diclofenac Potassium Powder for Oral Solution with concomitant drugs that are known to be potentially hepatotoxic (e.g. acetaminophen, certain antibiotics, antiepileptics).

Taro-Diclofenac Potassium Powder for Oral Solution is contraindicated in severe liver impairment or active liver disease. If there is a need to prescribe this drug in the presence of impaired liver function, it must be done under strict observation (see 2 Contraindications and 10.3 Pharmacokinetics, Special populations and conditions, Hepatic Insufficiency).Caution is advised when using Taro-Diclofenac Potassium Powder for Oral Solution in patients with hepatic porphyria, since Taro-Diclofenac Potassium Powder for Oral Solution may trigger an attack.

Immune

Aseptic Meningitis: Rarely, with some NSAIDs, the symptoms of aseptic meningitis (stiff neck, severe headaches, nausea and vomiting, fever or clouding of consciousness) have been observed. Patients with autoimmune disorders (systemic lupus erythematosus, mixed connective tissue diseases, etc.) seem to be pre-disposed. Therefore, in such patients, the healthcare provider must be vigilant to the development of this complication.

Anaphylactoid Reactions: As with NSAIDs in general, anaphylactoid reactions have occurred in patients without known prior exposure to Taro-Diclofenac Potassium Powder for Oral Solution. In post-marketing experience, rare cases of anaphylactic/ anaphylactoid reactions and angioedema have been reported in patients receiving Taro-Diclofenac Potassium Powder for Oral Solution. Taro-Diclofenac Potassium Powder for Oral Solution is contraindicated in patients with the ASA-triad. This symptom complex typically occurs in asthmatic patients who experience rhinitis with or without nasal polyps, or who exhibit severe, potentially fatal bronchospasm after taking ASA or other NSAIDs (see 2 Contraindications).

ASA-Intolerance: Taro-Diclofenac Potassium Powder for Oral Solution is contraindicated in patients with complete or partial syndrome of ASA- intolerance (rhinosinusitis, urticaria/angioedema, nasal polyps, asthma) in whom asthma, anaphylaxis, urticaria/angioedema, rhinitis or other allergic manifestations are precipitated by ASA or other NSAIDs. Fatal anaphylactoid reactions have occurred in such individuals. As well, individuals with the above medical problems are at risk of a severe reaction even if they have taken NSAIDs in the past without any adverse reaction (see 2 Contraindications).

Infection: Taro-Diclofenac Potassium Powder for Oral Solution, as with other NSAIDs, may mask signs and symptoms of an underlying infectious disease.

Monitoring and Laboratory Tests

Cardiovascular (Hypertension): Blood pressure should be monitored regularly during therapy with Taro-Diclofenac Potassium Powder for Oral Solution.

Hematologic: Patients on long-term treatment with NSAIDs, including Taro-Diclofenac Potassium Powder for Oral Solution, should have their hemoglobin, hematocrit, and blood cell count checked if they exhibit any signs or symptoms of anemia or blood loss.

Concurrent therapy of Taro-Diclofenac Potassium Powder for Oral Solution with anticoagulants requires close monitoring of the international normalized ratio (INR)/anticoagulation.

Hepatic: Patients with symptoms and/or signs of liver dysfunction, or in whom an abnormal liver function test has occurred, should be monitored carefully for evidence of the development of a more severe hepatic reaction while on therapy with Taro-Diclofenac Potassium Powder for Oral Solution. If abnormal liver tests persist or worsen, Taro-Diclofenac Potassium Powder for Oral Solution should be discontinued.

Pregnancy: If Taro-Diclofenac Potassium Powder for Oral Solution is administered in the middle (approximately 20 weeks) to the end of the second trimester, it is recommended that pregnant women on Taro-Diclofenac Potassium Powder for Oral Solution be closely monitored for amniotic fluid volume since Taro-Diclofenac Potassium Powder for Oral Solution may result in reduction of amniotic fluid volume and even oligohydramnios (see 3 Serious Warnings and Precautions Box; 7.1.1 Pregnancy). Taro-Diclofenac Potassium Powder for Oral Solution is contraindicated for use in the third trimester of pregnancy (see 2 Contraindications).

Renal: Renal function (serum creatinine and serum urea etc.) should be monitored in high-risk populations, such as the elderly, patients with advanced renal disease, patients with cardiovascular disease and diabetes mellitus, as well as in the setting of concomitant use of diuretics and ACE inhibitors (see 2 Contraindications). If abnormal renal tests persist or worsen, ELYXYB should be discontinued.

Patients on long-term treatment with NSAIDs, including ELYXYB, should have their electrolytes, such as serum potassium, checked regularly if they exhibit any signs or symptoms of renal disease.

Neurologic

Some patients may experience drowsiness, dizziness, blurred vision, vertigo, tinnitus, hearing loss, insomnia or depression with the use of NSAIDs, such as Taro-Diclofenac Potassium Powder for Oral Solution. If patients experience such adverse reaction(s), they should exercise caution in carrying out activities that require alertness.

Medication Overuse Headache: Overuse of acute migraine drugs (e.g., ergotamine, triptans, opioids, NSAIDs or combination of these) including Taro-Diclofenac Potassium Powder for Oral Solution, may lead to exacerbation of headache (medication overuse headache). Medication overuse headache may present as migraine-like daily headaches or as a marked increase in frequency of migraine attacks. Detoxification of patients, including withdrawal of the overused drugs and treatment of withdrawal symptoms (which often includes a transient worsening of headache) may be necessary.

Ophthalmologic

Blurred and/or diminished vision has been reported with the use of NSAIDs. If such symptoms develop, Taro-Diclofenac Potassium Powder for Oral Solution should be discontinued and an ophthalmologic examination performed. Ophthalmologic examination should be carried out at periodic intervals in any patient receiving Taro-Diclofenac Potassium Powder for Oral Solution for an extended period of time. Sun exposure in patients using Taro-Diclofenac Potassium Powder for Oral Solution might cause photosensitivity and vision changes. Patients should be advised to contact their physician for assessment and advice if this occurs.

Perioperative Considerations

See 2 Contraindications.

Renal

Long term administration of NSAIDs to animals has resulted in renal papillary necrosis and other abnormal renal pathology. In humans, there have been reports of acute interstitial nephritis, hematuria, low grade proteinuria and occasionally nephrotic syndrome.

During long-term therapy, kidney function should be monitored periodically (see 10.3 Pharmacokinetics, Special populations and conditions, Renal Insufficiency).

Renal impairment due to NSAID use is seen in patients with pre-renal conditions leading to reduction in

renal blood flow or blood volume. Under these circumstances, renal prostaglandins help maintain renal perfusion and glomerular filtration rate (GFR). In these patients, administration of a NSAID may cause a reduction in prostaglandin synthesis leading to impaired renal function. Patients at greatest risk of this reaction are those with pre-existing renal impairment (GFR < 60 mL/min or 1 mL/s), dehydrated patients, patients on salt restricted diets, those with congestive heart failure, cirrhosis, liver dysfunction, taking angiotensin-converting enzyme inhibitors, angiotensin-II receptor blockers, cyclosporin, diuretics, and those who are elderly. Serious or life-threatening renal failure has been reported in patients with normal or impaired renal function after short term therapy with NSAIDs. Even patients at risk who demonstrate the ability to tolerate a NSAID under stable conditions may decompensate during periods of added stress (e.g. dehydration due to gastroenteritis). Discontinuation of NSAIDs is usually followed by recovery to the pre-treatment state.

Caution should be used when initiating treatment with NSAIDs, such as Taro-Diclofenac Potassium Powder for Oral Solution, in patients with considerable dehydration. Such patients should be rehydrated prior to initiation of therapy. Caution is also recommended in patients with pre-existing kidney disease.

Advanced Renal Disease: Taro-Diclofenac Potassium Powder for Oral Solution is contraindicated in patients with advanced renal disease (see 2 Contraindications).

Fluid and Electrolyte Balance: Use of NSAIDs, such as Taro-Diclofenac Potassium Powder for Oral Solution, can promote sodium retention in a dose- dependent manner, which can lead to fluid retention and edema, and consequences of increased blood pressure and exacerbation of congestive heart failure. Thus, caution should be exercised in prescribing Taro-Diclofenac Potassium Powder for Oral Solution in patients with a history of congestive heart failure, compromised cardiac function, hypertension, increased age or other conditions predisposing to fluid retention (see 7 Warnings and Precautions, Cardiovascular).
Use of NSAIDs, such as Taro-Diclofenac Potassium Powder for Oral Solution , can increase the risk of hyperkalemia, especially in patients with diabetes mellitus, renal failure, increased age, or those receiving concomitant therapy with adrenergic blockers, angiotensin-converting enzyme inhibitors, angiotensin-II receptor antagonists, cyclosporin, or some diuretics.
Electrolytes should be monitored periodically (see 2 Contraindications).

Reproductive Health
The use of Taro-Diclofenac Potassium Powder for Oral Solution, as with any drug known to inhibit cyclooxygenase/prostaglandin synthesis, may impair fertility and is not recommended in women attempting to conceive. Therefore, in women who have difficulties conceiving, or who are undergoing investigation of infertility, withdrawal of Taro-Diclofenac Potassium Powder for Oral Solution should be considered.

Respiratory
ASA-induced asthma is an uncommon but very important indication of ASA and NSAID sensitivity. It occurs more frequently in patients with asthma who have nasal polyps.
Pre-existing asthma: In patients with asthma, seasonal allergic rhinitis, swelling of the nasal mucosa (i.e. nasal polyps), chronic obstructive pulmonary diseases or chronic infections of the respiratory tract (especially if linked to allergic rhinitis-like symptoms), reactions on NSAIDs like asthma exacerbations (so-called intolerance to analgesics / analgesics-asthma), Quincke's oedema or urticaria are more frequent than in other patients. Therefore, special precaution is recommended in such patients (readiness for emergency). This is applicable as well for patients who are allergic to other substances, e.g. with skin reactions, pruritus or urticaria.

Sensitivity/Resistance
Cross-sensitivity: Patients sensitive to one NSAID may be sensitive to any of the other NSAIDs as well.

Skin
Serious skin reactions: Use of some NSAIDs, such as Taro-Diclofenac Potassium Powder for Oral Solution, have been associated with rare post- market cases of serious, fatal or otherwise life-threatening skin reactions, including:

- drug reaction with eosinophilia and systemic symptoms (DRESS)
- Stevens-Johnson syndrome,
- toxic epidermal necrolysis,
- exfoliative dermatitis
- erythema multiforme
- generalized bullous fixed drug eruption (GBFDE)

Patients appear to be at higher risk for these events early in the course of therapy, with the onset of cases usually occurring within the first month of treatment. These reactions may be reversible if the causative agent is discontinued and appropriate treatment instituted. Patients should be advised that they should discontinue their NSAID at the first appearance of a skin rash, mucosal lesions or any other sign of hypersensitivity, and contact their physician immediately for assessment and advice, including which therapies to discontinue.
DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy, and/or facial swelling. Other clinical manifestations may include hepatitis, nephritis, hematological abnormalities, myocarditis, or myositis. Sometimes symptoms of DRESS may resemble an acute viral infection, and eosinophilia is often present. Because this disorder is variable in its presentation, other organ systems not noted here may be involved. It is important to note that early manifestations of hypersensitivity, such as fever or lymphadenopathy, may be present even though rash is not evident.
Use of Taro-Diclofenac Potassium Powder for Oral Solution may cause photosensitivity upon exposure to sunlight or UV light causing symptoms such as sunburn, skin rash, skin blisters, pruritus, erythema and discoloration.

7.1 Special Populations

7.1.1 Pregnancy

Taro-Diclofenac Potassium Powder for Oral Solution is contraindicated for use during the third trimester of pregnancy because of risk of premature closure of the ductus arteriosus and the potential to prolong parturition (see 2 Contraindications). Diclofenac Potassium Powder for Oral Solution readily crosses the human placental barrier. Caution is recommended in prescribing Taro-Diclofenac Potassium Powder for Oral Solution during the first and second trimesters of pregnancy, particularly from the middle to end of the second trimester of pregnancy (onset at approximately 20 weeks) due to possible fetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment or failure.

Published studies and post-marketing reports describe maternal NSAID use at approximately 20 weeks gestation or later in pregnancy associated with fetal renal dysfunction leading to oligohydramnios, and in some cases, neonatal renal impairment or failure. NSAIDs were shown to cause significant reduction in fetal urine production prior to reduction of amniotic fluid volume. There have also been a limited number of case reports of maternal NSAID use and neonatal renal dysfunction and renal impairment without oligohydramnios, some of which were irreversible, even after treatment discontinuation.

These adverse outcomes are seen, on average, after days to weeks of treatment, although oligohydramnios has been infrequently reported as soon as 48 hours after NSAID initiation. Complications of prolonged oligohydramnios may for example, include limb contractures and delayed lung maturation. In some post-marketing cases of impaired neonatal renal function, invasive procedures such as exchange transfusion or dialysis were required.

If after careful consideration of the benefit-risk, NSAID treatment is considered necessary to be administered anywhere from the middle (onset at approximately 20 weeks) to the end of the second

trimester of pregnancy, the use should be limited to the lowest effective dose and shortest duration possible. It is also recommended that ultrasound monitoring of amniotic fluid be considered if Taro-Diclofenac Potassium Powder for Oral Solution treatment extends beyond 48 hours and that NSAIDs treatment be discontinued if oligohydramnios occurs, followed by appropriate medical follow up.

Administration of diclofenac at the time of ovulation resulted in a long-lasting decrease in cervical mucus secretions in women with regular menstruation cycles which may affect fertility.

Inhibition of prostaglandin synthesis may adversely affect pregnancy and/or the embryo-fetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation after use of a prostaglandin synthesis inhibitor in early pregnancy.

In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-fetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenesis period.

The effects of diclofenac potassium on labor and delivery in pregnant women are unknown. In rat studies, maternal exposure to NSAIDs, as with other drugs known to inhibit prostaglandin synthesis, increased the incidence of dystocia, delayed parturition, and decreased pup survival.

7.1.2 Breastfeeding

Diclofenac potassium is excreted in human milk, and is contraindicated in breastfeeding women (see 2 Contraindications).

7.1.3 Pediatrics

Pediatrics (<18 years of age): Safety and efficacy of Taro-Diclofenac Potassium Powder for Oral Solution have not been studied in pediatric patients below the age of 18 years, and its use in this population is contraindicated (see 2 Contraindications).

7.1.4 Geriatrics

Geriatrics (> 65 years of age): Patients older than 65 years (referred to in this document as older or elderly) and frail or debilitated patients are more susceptible to a variety of adverse reactions from NSAIDs. The incidence of these adverse reactions increases with dose and duration of treatment. In addition, these patients are less tolerant to ulceration and bleeding. Most reports of fatal GI events are in this population. Older patients are also at risk of lower esophageal injury including ulceration and bleeding. For such patients, consideration should be given to a starting dose lower than the one usually recommended, with individual adjustment when necessary and under close supervision (see 4.2 Recommended Dose and Dosage Adjustment).

8. Adverse Reactions

8.1 Adverse Reaction Overview

Gastrointestinal, dermatological, CNS and hepatic adverse reactions are the most commonly seen with diclofenac-containing products. The most severe gastrointestinal adverse reactions observed were ulcer and hemorrhage, while the most severe dermatological, albeit rare, reactions observed with diclofenac were erythema multiforme (Stevens-Johnson Syndrome and Toxic epidermal necrolysis). Fatalities have occurred on occasion, particularly in the elderly.

8.2 Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. Therefore, the frequencies of adverse reactions observed in the clinical trials may not reflect frequencies observed in clinical practice and should not be compared to frequencies reported in clinical trials of another drug.

The safety of a single dose of diclofenac potassium powder for oral solution was evaluated within two placebo-controlled Phase III clinical trials. A total of 634 subjects were exposed to treatment with diclofenac potassium powder for oral solution. Of those subjects who ranged from 18 to 65 years of age, 543 (85.6%) were female.
The most commonly reported Adverse Events (AEs) in the diclofenac potassium powder for oral solution treatment group were in the system organ classes of gastrointestinal disorders, nervous system disorders and psychiatric disorders.
A summary of the most commonly reported treatment-emergent events is provided in Table 2.

Table 2 - Treatment-Emergent Adverse Events with Incidences of > 1% by Treatment Group Following a Single Dose of diclofenac potassium powder for oral solution

System Organ Class/MedDRA Preferred Term	Placebo n=646 (%)	Diclofenac potassium powder for oral solution n=634 (%)
Gastrointestinal Disorders		
Abdominal pain upper	4 (0.6)	5 (0.8)
Dyspepsia	6 (0.9)	7 (1.1)
Nausea	18 (2.8)	25 (3.9)
Vomiting	5 (0.8)	8 (1.3)
Nervous System Disorders		
Dysgeusia	2 (0.3)	3 (0.5)
Psychiatric Disorders		
Insomnia	0 (0)	3 (0.5)
Restlessness	0 (0)	3 (0.5)

8.1. Less Common Clinical Trial Adverse Reactions

Less Common Clinical Trial Treatment--Emergent Adverse Events (<1%)

Gastrointestinal disorders: Abdominal distension, Abdominal pain, Glossitis, Hypoaesthesia oral, Paraesthesia oral, Abdominal discomfort

General disorders and administration site conditions: Asthenia, Fatigue, Feeling abnormal, Irritability
Infections and infestations: Dysentery, Sinusitis

Injury, poisoning and procedural complications: Arthropod sting

Investigations: Heart rate increased

Musculoskeletal and connective tissue disorders: Musculoskeletal chest pain

Nervous system disorders: Ageusia, Headache, Hyperaesthesia, Paraesthesia, Tremor

Psychiatric disorders: Agitation, Anxiety, Confusional state, Deja vu, Nervousness

Respiratory, thoracic and mediastinal disorders: Cough, Throat irritation

Skin and subcutaneous tissue disorders: Erythema, Hyperhidrosis, Urticaria

Vascular disorders: Flushing

8.4 Abnormal Laboratory Findings: Hematologic, Clinical Chemistry, and Other Quantitative Data

See 7 Warnings and Precautions, Hematologic, Blood dyscrasias.

8.5 Post-Market Adverse Reactions

The following adverse events not described elsewhere in the label have been identified during post-approval use of diclofenac-containing products including diclofenac potassium powder for oral solution. These reactions are reported voluntarily from a population of uncertain size, and it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Table 3 - Post-Marketing Adverse Events for Diclofenac-containing Products

System Organ Class	Adverse Events
Blood and lymphatic system disorders	Agranulocytosis, Anaemia, Aplastic anaemia, Eosinophilia, Hemolytic anaemia, Leukopenia, Lymphadenopathy, Pancytopenia, Thrombocytopenia
Cardiac disorders	Angina pectoris, Arrhythmia, Cardiac Arrest, Congestive heart failure, Myocardial infarction, Palpitations, Tachycardia
Ear and labyrinth disorders	Hearing impaired, Tinnitus, Vertigo
Eye disorders	Vision blurred, Conjunctivitis
Gastrointestinal disorders	Colitis, Colonic stenosis, Constipation, Eructation, Flatulence, Gastric ulcer, Gastritis, Gastrointestinal disorder, Gastrointestinal haemorrhage, Gastrointestinal ulcer, Glossitis, Gastrointestinal perforation, Haematochezia, Heartburn, Haematemesis, Melaena, Obstruction gastric, Oesophagitis, Pancreatitis, Peptic ulcer, Rectal haemorrhage, Stomatitis
General disorders and administration site conditions	Drug interaction, Death, Malaise, Multi-organ failure, Oedema, Product taste abnormal, Pyrexia
Hepatobiliary disorders	Hepatitis
Infections and infestations	Cystitis, Infection, Meningitis, Pneumonia, Sepsis, Septic shock
Investigations	Bleeding time prolonged, Heart rate decreased, Hepatic enzyme increased
Metabolism and nutrition disorders	Appetite disorder, Hyperglycaemia, Metabolic acidosis, Weight fluctuation
Nervous system disorders	Coma, Seizure, Migraine, Syncope
Psychiatric disorders	Confusional state, Depression, Abnormal dreams, Hallucination
Renal and urinary disorders	Dysuria, Haematuria, Oliguria, Polyuria, Proteinuria, Renal impairment, Tubulointerstitial nephritis, Renal failure
Respiratory, thoracic and mediastinal disorders	Asthma, Dyspnea, Epistaxis, Haemoptysis, Pulmonary hypertension, Respiratory depression
Skin and subcutaneous tissue disorders	Alopecia, Dermatitis exfoliative, Drug reaction rash with eosinophilia and systemic symptoms, Ecchymosis, fixed drug eruption Photosensitivity reaction, Pruritus, Purpura, Rash, Stevens-Johnson syndrome, Toxic epidermal necrolysis
Vascular disorders	Hypertension, Hypotension, Vasculitis

9. Drug Interactions

9.2 Drug Interactions Overview

Effect of Other Drugs on the Metabolism of diclofenac: Co-prescribing diclofenac with potent CYP2C9 inhibitors could result in a significant increase in peak plasma concentrations and exposure to diclofenac due to inhibition of diclofenac metabolism. Diclofenac is metabolized predominantly by CYP2C9. Caution is recommended when co-prescribing Taro-Diclofenac Potassium Powder for Oral Solution with potent CYP2C9 inhibitors, including sulfinpyrazone and voriconazole.

9.3 Drug-Behaviour Interactions

When alcohol is consumed concomitantly with NSAIDS, there may be an increased risk of gastrointestinal side effects, including ulceration or hemorrhage (See 7 Warnings and Precautions, Gastrointestinal)

9.4 Drug-Drug Interactions

The drugs listed in this table are based on either drug interaction case reports or studies, or potential interactions due to the expected magnitude and seriousness of the interaction (i.e., those identified as contraindicated).

Table 4 - Established or Potential Drug-Drug Interactions

Non-proprietary names of the drug products	Source of evidence	Effect	Clinical comment
Acetaminophen	T	There may be an increased risk of adverse renal effects when administered concomitantly with NSAIDs.	Physicians should caution their patients to avoid taking nonprescription acetaminophen-containing products while using Taro-Diclofenac Potassium Powder for Oral Solution

Non-proprietary names of the drug products	Source of evidence	Effect	Clinical comment
Acetylsalicylic acid (ASA/Aspirin) or other NSAIDs	CT	Some NSAIDs (e.g. diclofenac potassium) may interfere with the anti-platelet effects of low dose ASA, possibly by competing with ASA for access to the active site of cyclooxygenase-1. Taro-Diclofenac Potassium Powder for Oral Solution (diclofenac potassium) should not be used concomitantly with diclofenac sodium since both exist in plasma as the same active organic anion. Concomitant administration of diclofenac and other systemic NSAIDs or corticosteroids may increase the frequency of gastrointestinal adverse events.	The use of Taro-Diclofenac Potassium Powder for Oral Solution in addition to any other NSAID, including over- the counter ones (such as ASA and diclofenac potassium) for analgesic and/or anti-inflammatory effects is NOT recommended because of the absence of any evidence demonstrating synergistic benefits and the potential risk for additive adverse reactions such as GI toxicity, including inflammation, bleeding and ulceration. The exception is the use of low dose (81 mg daily) ASA for cardiovascular protection, when another NSAID is being used for its analgesic/anti-inflammatory effect, keeping in mind that combination NSAID therapy is associated with additive adverse reactions. Thus, patients receiving concomitant treatment with diclofenac potassium powder for oral solution and any other NSAID (including ASA) should be monitored for signs of bleeding.
Anti-coagulants	T	Concomitant administration of anti-coagulants (e.g. warfarin) with NSAIDs may increase risk for serious GI bleeding (see 7 Warnings and Precautions, Hematologic, Anti-coagulants)	Anticoagulation / INR should be monitored in patients taking anticoagulants, since these patients are at an increased risk of bleeding complications

Non-proprietary names of the drug products	Source of evidence	Effect	Clinical comment
Anti-hypertensives	T	NSAIDs may diminish the anti-hypertensive effect of Angiotensin Converting Enzyme (ACE) inhibitors. Combinations of ACE inhibitors, angiotensin-II antagonists, or diuretics with NSAIDs might have an increased risk for acute renal failure and hyperkalemia.	The combination should be administered with caution especially in the elderly. Blood pressure and renal function (including electrolytes) should be monitored more closely in this situation, as occasionally there can be a substantial increase in blood pressure (see 7 Warnings and Precautions, Renal).
Anti-platelet Agents (including ASA)	T	There is an increased risk of bleeding, via inhibition of platelet function, when antiplatelet agents are combined with NSAIDs, including diclofenac potassium (see 7 Warnings and Precautions, Hematologic, Anti-platelet Effects).	Monitor patients for signs of bleeding
Cyclosporine	T	Diclofenac Potassium, like other NSAIDs, may affect renal prostaglandins and increase the toxicity of certain drugs. Therefore, concomitant therapy with diclofenac potassium powder for oral solution may increase cyclosporine's nephrotoxicity.	Use caution when diclofenac potassium powder for oral solution is administered concomitantly with cyclosporine.
Digoxin	T	Diclofenac, like other NSAIDs, may affect renal prostaglandins and increase plasma concentration of digoxin.	Use caution when diclofenac potassium powder for oral solution is administered, and monitoring of serum digoxin level is also recommended.

Non-proprietary names of the drug products	Source of evidence	Effect	Clinical comment
Diuretics	CT	Clinical studies as well as post-marketing observations have shown that NSAIDs can reduce the effect of diuretics (see 7 Warnings and Precautions, Renal).	Observe patients for signs of worsening renal function, in addition to assuring diuretic efficacy including antihypertensive effects.
Glucocorticoids	CT	Some studies have shown that the concomitant use of NSAIDs and oral glucocorticoids increases the risk of GI adverse events such as ulceration and bleeding.	Monitor patients, particularly those over 65 years of age, for signs of bleeding. See 7 Warnings and Precautions, Gastrointestinal.
Lithium	CT	NSAIDs have produced 15% elevations of plasma lithium levels and a 20 % reduction in renal lithium clearance. These effects have been attributed to inhibition of renal prostaglandin synthesis by the NSAID.	When diclofenac potassium powder for oral solution and lithium are administered concurrently, observe patients carefully for signs of lithium toxicity. Monitoring of plasma lithium concentrations is advised when stopping or starting a NSAID.
Methotrexate	C	NSAIDs have been reported to competitively inhibit methotrexate accumulation in rabbit kidney slices. This indicates that NSAIDs may enhance the toxicity of methotrexate.	Caution should be exercised when diclofenac potassium powder for oral solution is administered less than 24 hours before or after treatment with methotrexate.
Oral Hypoglycemics	C	There are isolated reports of hyperglycemia and hypoglycemia when the drugs are taken together which necessitated a change in oral hypoglycemic drug dose.	
Phenytoin	T	An expected increase in exposure to phenytoin.	When using phenytoin concomitantly with diclofenac, monitoring of phenytoin plasma concentrations is recommended.

Non-proprietary names of the drug products	Source of evidence	Effect	Clinical comment
Probenecid	T	Probenecid may decrease the excretion and increase serum concentrations of NSAIDs possibly enhancing effectiveness and/or increasing potential for toxicity.	Concurrent therapy of NSAIDs with probenecid requires close monitoring to be certain that no change in dosage is necessary.
Quinolone antibacterials	C	There have been isolated reports of convulsions which may have been due to concomitant use of quinolones and NSAIDs.	
Selective Serotonin Reuptake Inhibitors (SSRIs) and Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs)	T	Concomitant administration of NSAIDs, including diclofenac potassium powder for oral solution , and SSRIs and SNRIs may increase the risk of gastrointestinal ulceration and bleeding (see 7 Warnings and Precautions, Gastrointestinal).	Monitor patients for signs of bleeding.
Tacrolimus	T	Nephrotoxicity of tacrolimus may be increased because of the effect of NSAIDs on renal prostaglandins.	Caution is recommended when co-prescribing Taro-Diclofenac Potassium Powder for Oral Solution with tacrolimus.

C = Case Study; CT = Clinical Trial; T = Theoretical

9.5 Drug-Food Interactions

Whereas taking diclofenac potassium powder for oral solution with a meal may cause a delay in total absorption as compared to taking diclofenac potassium powder for oral solution on an empty stomach, food may reduce the risk of gastro-intestinal side effects. A high fat meal may be associated with decreased peak plasma levels (C_{max}) of diclofenac (see 10.3 Pharmacokinetics, Absorption).

9.6 Drug-Herb Interactions

Interaction of Taro-Diclofenac Potassium Powder for Oral Solution with herbal products has not been studied.

9.7 Drug-Laboratory Test Interactions

Diclofenac increases platelet aggregation time but does not affect bleeding time, plasma thrombin clotting time, plasma fibrinogen, or factors V and VII to XII. Statistically significant changes in prothrombin

and partial thromboplastin times have been reported in normal volunteers. The mean changes were observed to be less than 1 second in both instances. Persistently abnormal or worsening renal, hepatic or hematological test values should be followed up carefully since they may be related to diclofenac potassium powder for oral solution therapy.

10. Clinical Pharmacology

10.1 Mechanism of Action

Like other non-selective NSAIDs, diclofenac exerts its principal effect by inhibiting the cyclo-oxygenase (COX) enzymes COX-1 and COX-2. This inhibition leads to decreases in prostaglandin production; prostaglandins play a major role in causing inflammation and pain.

10.2 Pharmacodynamics

Diclofenac is a phenyl-acetic acid derivative non-selective NSAID possessing analgesic, antipyretic, and anti-inflammatory properties, as shown in various pharmacological models. The mechanism responsible for these pharmacological effects is mainly the inhibition of prostaglandin synthesis. Diclofenac is a potent inhibitor of cyclo-oxygenase (COX) enzymes COX-1 and COX-2 *in vitro* and *in vivo* which decreases the synthesis of prostaglandins, prostacyclin, and thromboxane products. Prostaglandins play a major role in causing inflammation, pain, and fever, and adaptive and protective reactions in many organs and (inflamed) tissues.
The anti-inflammatory potency of diclofenac potassium was assessed by testing inhibition of paw edema (carrageenan solution) in rats.
The antinociceptive effect of diclofenac potassium was assessed by the writhing test in mice.

10.3 Pharmacokinetics

Absorption

Diclofenac is almost completely absorbed after oral administration. However, due to first-pass metabolism, only about 50 to 60% of the absorbed dose is systemically available in the unchanged form.

In fasted normal healthy subjects, significantly measurable plasma levels were observed within 5 minutes of dosing with diclofenac potassium powder for oral solution Time to reach maximum plasma levels (T_{max}) were achieved after approximately 15 minutes (range: 10 to 40 minutes) in fasting conditions, while under fed conditions T_{max} was approximately 10 minutes (range: 5 minutes to 4 hours). Mean area under the plasma curve (AUC) values for diclofenac were 1254.6 and 1084.2 ng*hr/mL for diclofenac potassium powder for oral solution under fasting and fed conditions, respectively. Mean maximum concentration (C_{max}) values for diclofenac were 1618.3 and 505.5 ng/mL for diclofenac potassium powder for oral solution under fasting and fed conditions, respectively. A high fat meal had no significant effect on the extent of diclofenac absorption; however, it caused a reduction in the C_{max} of approximately 70%.

Distribution

The apparent volume of distribution of diclofenac is 0.12 to 0.17 L/kg. Diclofenac is more than 99% bound to human serum proteins, primarily to albumin.

Metabolism

Orally administered diclofenac is subject to first-pass metabolism and only 50 to 60% of the drug reaches the systemic circulation in the unchanged form.

Five major hydroxylated metabolites have been identified in human plasma and urine. The metabolites include 3'-hydroxy, 4'-hydroxy, 5-hydroxy, 4',5-dihydroxy-, and 3'-hydroxy-4'-methoxy diclofenac. The major diclofenac metabolite, 4'-hydroxy diclofenac, has very weak pharmacologic activity. The formation of 4'-hydroxy diclofenac is primarily mediated by CPY2C9. Both diclofenac and its oxidative metabolites

undergo glucuronidation or sulfation followed by biliary excretion. Acyl glucuronidation mediated by UGT2B7 and oxidation mediated by CPY2C8 may also play a role in diclofenac metabolism. CYP3A4 is responsible for the formation of minor metabolites, 5-hydroxy and 3'-hydroxy diclofenac. In patients with renal impairment, peak concentrations of metabolites 4'-hydroxy and 5- hydroxyl diclofenac were respectively approximately 50% and 4% of the parent compound after single oral dosing compared to 27% and 1% in normal healthy subjects.

Elimination

Plasma clearance of diclofenac is 263 ± 56 mL/min. Diclofenac is eliminated principally through hepatic metabolism and subsequent urinary and biliary excretion of the glucuronide and the sulfate conjugates of the metabolites. About 1% of an oral dose is excreted unchanged in urine. Approximately 65% of the dose is excreted in the urine and approximately 35% in the bile as conjugates of unchanged diclofenac plus metabolites.

The terminal half-life of unchanged diclofenac is approximately 2 hours.

Special populations and conditions

- **Hepatic Insufficiency:** There is no information available regarding the use of diclofenac potassium powder for oral solution in patients with hepatic impairment.

  Since the liver metabolizes almost 100% of diclofenac, patients with any degree of hepatic impairment should be considered for treatment with diclofenac potassium powder for oral solution only if the benefits outweigh the risks (see 2 Contraindications and 7 Warnings and Precautions, Hepatic/Biliary/Pancreatic).

- **Renal Insufficiency:** There is no information available regarding the use of diclofenac potassium powder for oral solution in patients with renal impairment.

  Caution is advised while administering diclofenac potassium powder for oral solution to patients with any degree of impaired kidney function (see 7 Warnings and Precautions, Renal). Diclofenac potassium powder for oral solution is contraindicated in patients with severely impaired or deteriorating renal function (creatinine clearance < 30 mL/min (0.5 mL/sec)) (see 2 Contraindications).

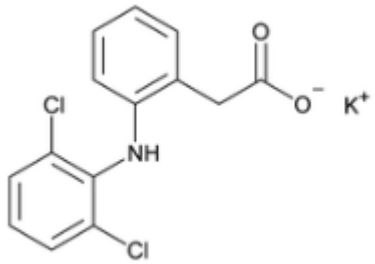
11. Storage, Stability, and Disposal

Store at room temperature (15°C to 30°C).

Part 2: Scientific Information

13. Pharmaceutical Information

Drug Substance

Non-proprietary name of the drug substance:	Diclofenac Potassium
Chemical name:	Potassium-[o-[(2,6-dichlorophenyl)-amino]-phenyl]-acetate.
Molecular formula and molecular mass:	$C_{14}H_{10}Cl_2NKO_2$ and 334.25 g/mol
Structural formula:	
Physicochemical properties:	Diclofenac potassium is a white or slightly yellowish, crystalline powder, slightly hygroscopic. Diclofenac potassium is sparingly soluble in water, freely soluble in methanol, soluble in ethanol (96%), slightly soluble in acetone. The melting point is 315.15 – 315.55ºC. The PKa is 4.0 ± 0.2 at 25ºC in water

14. Clinical Trials

14.1 Clinical Trials by Indication

The efficacy of diclofenac potassium powder for oral solution in the acute treatment of migraine headache has been demonstrated in a randomized, double-blind, placebo-controlled, parallel-group trial. Patients enrolled in the trial were predominantly female (85%) and white (80%), with a mean age of 40 years (range: 18 to 65). A total of 343 migraine patients were treated with diclofenac potassium powder for oral solution in the study.

Subjects treated one migraine attack with one single dose of either diclofenac potassium powder for oral solution or placebo. Patients treated a migraine of moderate to severe pain.

The percentage of subjects who were pain free 2 hours later was assessed. Associated symptoms of nausea, photophobia, and phonophobia were also evaluated 2 hours post-dose. Headache response (defined as a reduction in headache severity from moderate or severe pain to mild or no pain) 2 hours after treatment was also recorded.

Study results

The percentage of subjects achieving pain freedom 2 hours after treatment was significantly greater ($p < 0.001$) in patients who received diclofenac potassium powder for oral solution (25%) compared with those who received placebo (10%). In addition, there was a significant decreased incidence of nausea, photophobia and phonophobia in patients treated with diclofenac potassium powder for oral solution as compared to placebo 2 hours after treatment. Headache response 2 hours post-dose was also significantly superior in patients who received diclofenac potassium powder for oral solution compared to those who

received placebo.

Additionally, it was demonstrated that diclofenac potassium powder for oral solution had a rapid onset of action (within 30 minutes of dosing). The efficacy and safety of diclofenac potassium powder for oral solution was unaffected by age or gender of the patient.

16. Non-Clinical Toxicology

Since the same active, diclofenac, is absorbed from the potassium and sodium salts, toxicological finding with diclofenac sodium are representative of systemic toxicities with diclofenac potassium.

Genotoxicity

Diclofenac sodium was not genotoxic in *in vitro* (reverse mutation in bacteria [Ames], mouse lymphoma thymidine kinase) or in *in vivo* (including dominant lethal and male germinal epithelial chromosomal aberration in Chinese hamster) assays.

Carcinogenicity

Long term carcinogenicity studies in rats given diclofenac sodium up to 2 mg/kg/day (less than the recommended human dose [RHD] of 50 mg/day on a body surface area [mg/m^2] basis) have revealed no significant increases in tumor incidence. There was a slight increase in benign mammary fibroadenomas in mid-dose treated (0.5 mg/kg/day or 3 mg/m^2/day) female rats (high-dose females had excessive mortality), but the increase was not significant for this common rat tumor. A 2-year carcinogenicity study conducted in mice employing diclofenac sodium at doses up to 0.3 mg/kg/day (less than the RHD on a mg/m^2 basis) in males and 1 mg/kg/day (less than the RHD on a mg/m^2 basis) in females did not reveal any oncogenic potential.

Reproductive and developmental toxicology

Diclofenac sodium administered to male and female rats at 4 mg/kg/day (less than the RHD on a mg/m^2 basis) did not affect fertility.

17 Supporting Product Monographs

Pr**CAMBIA®** (Diclofenac potassium powder for oral solution, 50 mg of diclofenac potassium), Control number 298910, Product Monograph, Aralez Pharmaceuticals Canada Inc., (2025-11-05).

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]Taro-Diclofenac Potassium Powder for Oral

Diclofenac potassium powder for oral solution USP

This Patient Medication Information is written for the person who will be taking **Taro-Diclofenac Potassium Powder for Oral Solution**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **Taro-Diclofenac Potassium Powder for Oral Solution**, talk to a healthcare professional.

Serious warnings and precautions box

Heart and blood vessel problems:

- Taro-Diclofenac Potassium Powder for Oral Solution can cause heart and blood vessel problems that can lead to death, such as:
    - **Myocardial infarction** (heart attack);
    - **Stroke** (bleeding or blood clot in the brain);
    - **Hypertension** (high blood pressure); and
    - **Congestive heart failure** (heart does not pump blood as well as it should).
- The risk of having heart problems is higher if you take Taro-Diclofenac Potassium Powder for Oral Solution for long periods of time and/or at higher doses and/or if you have heart disease when you start Taro-Diclofenac Potassium Powder for Oral Solution. To minimize this risk, you should only take Taro-Diclofenac Potassium Powder for Oral Solution for the fewest number of days per month, as needed.
- You and your healthcare professional should closely monitor your health for signs or symptoms of heart or blood vessel problems during your treatment with Taro-Diclofenac Potassium Powder for Oral Solution.

Gastrointestinal problems: Taro-Diclofenac Potassium Powder for Oral Solution can cause stomach and intestine problems like ulcers, inflammation, bleeding, holes/perforation, blockage or pain. This risk increases when Taro-Diclofenac Potassium Powder for Oral Solution is taken with acetylsalicylic acid (ASA).

Pregnancy:

- DO NOT take Taro-Diclofenac Potassium Powder for Oral Solution if you are pregnant and in a later stage of pregnancy (i.e., 28 weeks or later).
- If you are pregnant and in an earlier stage of pregnancy (i.e., less than 28 weeks) only take Taro-Diclofenac Potassium Powder for Oral Solution if you are told to do so by your healthcare professional.
- Medicines like Taro-Diclofenac Potassium Powder for Oral Solution may cause harm to you and your unborn baby. Your healthcare professional will need to closely monitor your health and that of your unborn baby (including your amniotic fluid levels) if they prescribe you Taro-Diclofenac Potassium Powder for Oral Solution during this time.

- Tell your healthcare professional right away if you become pregnant, think you might be pregnant or are planning to get pregnant during your treatment with Taro-Diclofenac Potassium Powder for Oral Solution

What Taro-Diclofenac Potassium Powder for Oral Solution is used for:

Taro-Diclofenac Potassium Powder for Oral Solution is used in adults (18 years of age and older) for treatment of a migraine headache attack.

Taro-Diclofenac Potassium Powder for Oral Solution should not be used to try to prevent or reduce the number of headaches you experience. Taro-Diclofenac Potassium Powder for Oral Solution should not be used to treat pain other than that associated with migraine.

How Taro-Diclofenac Potassium Powder for Oral Solution works:

Taro-Diclofenac Potassium Powder for Oral Solution belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It can reduce the chemicals produced by your body which cause pain and swelling.

The ingredients in Taro-Diclofenac Potassium Powder for Oral Solution are:

Medicinal ingredient: Diclofenac potassium

Non-medicinal ingredients: Aspartame (equivalent to 25 mg phenylalanine), glyceryl dibehenate, mannitol, modified food starch, Natural & Artificial peppermint flavour, monoammonium glycyrrhizinate, potassium bicarbonate and saccharin sodium.

Taro-Diclofenac Potassium Powder for Oral Solution comes in the following dosage form:

Powder for oral solution: 50 mg of diclofenac potassium per sachet.

Do not use Taro-Diclofenac Potassium Powder for Oral Solution if:

- you recently had, or are planning to have, heart bypass surgery.
- you have severe, uncontrolled heart failure.
- you have bleeding in the brain or other bleeding disorders.
- you are pregnant and in a later stage of pregnancy (i.e., 28 weeks or later).
- you are currently breastfeeding or planning to breastfeed.
- you are allergic to diclofenac potassium or to any of the other ingredients in Taro-Diclofenac Potassium Powder for Oral Solution.
- you have a history of asthma, hives, growths in your nose, sinus swelling or symptoms of an allergic reaction after taking acetylsalicylic acid (ASA) or other NSAIDs.
- you have an active stomach or intestinal ulcer.
- you have active bleeding from the stomach or gut.
- you have inflammatory bowel disease (e.g., Crohn's disease or ulcerative colitis).
- you have severe or active liver disease.
- you have severe or worsening kidney disease.
- you were told by a healthcare professional that you have high levels of potassium in your blood.
- you are under 18 years of age.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Taro-Diclofenac Potassium Powder for Oral Solution. Talk about any health conditions or problems you

may have, including if you:

- are 65 years of age or older.
- have a condition that makes you physically weak.
- are currently taking any other medicines.
- have high blood pressure, high cholesterol or diabetes.
- have, or have had, heart attacks, chest pain, heart disease, stroke or heart failure.
- have poor blood flow to your extremities (like your hands and feet).
- smoke or used to smoke.
- drink a lot of alcohol.
- have a stomach infection.
- have liver or kidney problems, urinary problems, are dehydrated or on a salt-restricted diet.
- have a history of ulcer or bleeding from the stomach or gut (small or large intestine).
- have other bleeding or blood problems.
- ever had bleeding in the brain.
- have a family history of allergy to NSAIDs, such as acetylsalicylic acid (ASA), celecoxib, diclofenac, diflunisal, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac, mefenamic acid, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, rofecoxib, sulindac, tenoxicam, tiaprofenic acid, tolmetin, or valdecoxib (NOT a complete list).
- have asthma or other breathing problems.
- are pregnant, think you might be pregnant or planning on becoming pregnant.
- have immune system problems.
- have porphyria (a rare genetic condition that affects the nervous system and skin).
- have a condition called phenylketonuria, as Taro-Diclofenac Potassium Powder for Oral Solution contains aspartame (equivalent to 25 mg phenylalanine per sachet).

Other warnings you should know about:

Taro-Diclofenac Potassium Powder for Oral Solution can cause serious side effects, including:

- **Blood and bleeding problems:**
  - Taro-Diclofenac Potassium Powder for Oral Solution can cause blood problems (i.e., low levels of platelets, red or white blood cells), bleeding and prolonged bleeding.
  - Taking Taro-Diclofenac Potassium Powder for Oral Solution with the following medicines can increase the risk of bleeding:
    - Anticoagulants (prevents blood clots), corticosteroids (anti-inflammatory), or antidepressants like selective serotonin reuptake inhibitors (SSRIs).

- **Serious skin reactions:** In rare cases, serious, life-threatening and fatal allergic and skin reactions have been reported with some NSAIDs, such as Taro-Diclofenac Potassium Powder for Oral Solution. These skin problems most often happen during the first month of treatment. Stop taking Taro-Diclofenac Potassium Powder for Oral Solution and tell your healthcare professional **immediately** if you notice any allergic reactions or changes in your skin during treatment.

- **Sunlight sensitivity:** Taro-Diclofenac Potassium Powder for Oral Solution might cause you to become more sensitive to sunlight. Sunlight or sunlamps may cause sunburn, skin blisters, rash, redness, itching or discolouration, or changes to your vision such as light sensitivity. If you have a reaction from the sun, talk to your healthcare professional.

See **Serious side effects and what to do about them** table for more information on these and other serious side effects.

Overuse of Taro-Diclofenac Potassium Powder for Oral Solution: As with other migraine treatments, repeated use of Taro-Diclofenac Potassium Powder for Oral Solution can cause daily headaches or make your migraine headaches worse. Ask your healthcare professional if you think this is the case for you. You may need to stop using Taro-Diclofenac Potassium Powder for Oral Solution to correct the problem.

Check-ups and testing: You will have regular visits with your healthcare professional during treatment with Taro-Diclofenac Potassium Powder for Oral Solution. They will:

- Check your blood pressure.
- Check your eyes. Taro-Diclofenac Potassium Powder for Oral Solution can cause blurred or reduced vision.
- Do blood and urine tests to check your liver, kidney and blood health.

Surgery: Tell any doctor, dentist, pharmacist or healthcare professional that you see, that you are taking this medicine. This is especially important if you will be having heart surgery.

Driving and using machinery: Taro-Diclofenac Potassium Powder for Oral Solution may cause eye or nervous system problems. This includes tiredness, trouble sleeping, blurred vision, spinning or dizziness (vertigo), hearing problems or depression. Be careful about driving or doing activities that require you to be alert. If you become drowsy, dizzy, light-headed or have blurred vision after taking Taro-Diclofenac Potassium Powder for Oral Solution, do NOT drive or operate machinery.

Fertility in women: Taro-Diclofenac Potassium Powder for Oral Solution may affect your fertility. This means that it may be difficult for you to have a child. If you have trouble having a child, you might need to stop taking Taro-Diclofenac Potassium Powder for Oral Solution. Talk to your healthcare professional if you have any questions about this.

Adults (65 years of age or older): Side effects like gastrointestinal problems may happen more often. Your healthcare professional might have you start with a lower dose of Taro-Diclofenac Potassium Powder for Oral Solution. They will monitor your health during and after treatment.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Taro-Diclofenac Potassium Powder for Oral Solution:

- other medicines containing diclofenac. Do NOT take these medicines when you take Taro-Diclofenac Potassium Powder for Oral Solution.
- acetylsalicylic acid (ASA) or other NSAIDs, used to treat pain, fever and inflammation, like celecoxib, ibuprofen, naproxen, indomethacin, ketorolac, meloxicam.
- medicines known as “strong CYP2C9 inhibitors” like sulfinpyrazone, voriconazole.
- medicines used as blood thinners or to prevent blood clots like warfarin, ASA, clopidogrel.
- medicines used to treat high blood pressure like enalapril, ramipril, candesartan, irbesartan, propranolol, lisinopril, metoprolol, losartan, valsartan, perindopril.
- medicines used to lower the risk of organ rejection like tacrolimus and cyclosporine.
- medicines used to treat depression like citalopram, fluoxetine, paroxetine, sertraline.
- medicines used to move extra fluid and salt out of your body (also known as diuretics).
- corticosteroids (including glucocorticoids such as prednisone), used to treat inflammation and

overactive immune system responses.
- certain antibiotics, used to treat bacterial infection, like ciprofloxacin, levofloxacin and moxifloxacin.
- oral hypoglycemics, used to treat diabetes.
- lithium, used to treat manic episodes in bipolar disorder.
- methotrexate, used to treat inflammation caused by arthritis.
- phenytoin, used to treat seizures.
- probenecid, used to treat gout.
- acetaminophen, used to treat fever and pain. Do NOT take this medicine when you take Taro-Diclofenac Potassium Powder for Oral Solution.
- digoxin, used to treat heart disorders.
- alcohol.

How to take Taro-Diclofenac Potassium Powder for Oral Solution:

- Take Taro-Diclofenac Potassium Powder for Oral Solution exactly as your healthcare professional has told you.
- Do NOT take more of it, do NOT take it more often and do NOT take it for a longer period of time than your healthcare professional recommended.
- Take Taro-Diclofenac Potassium Powder for Oral Solution for the fewest number of days per month. This is to avoid potential side effects that may affect your heart, blood vessels, stomach or intestines. Your risk of experiencing these side effects may increase if you are elderly, have other diseases or take other medications.
- This medication has been prescribed specifically for you. Do NOT give it to anyone else. It may harm them, even if their symptoms seem to be similar to yours.

Directions for use:
- Open individual dose sachet only when ready to use.
- Empty the contents of one individual dose sachet into 30 to 60 mL (1 to 2 ounces) of water.
- Do not use liquids other than water.
- Mix to ensure that the powder is completely dissolved.
- Drink the water-powder mixture immediately after mixing.
- Taking Taro-Diclofenac Potassium Powder for Oral Solution with a meal may delay pain relief. However, food may reduce possible stomach and intestinal side effects.

Usual dose:

Adult dosage: One sachet at any time during a migraine attack.

Overdose:

If you think you, or a person you are caring for, have taken too much Taro-Diclofenac Potassium Powder for Oral Solution, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll- free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Possible side effects from using Taro-Diclofenac Potassium Powder for Oral Solution:

These are not all the possible side effects you may have when taking Taro-Diclofenac Potassium Powder for Oral Solution. If you experience any side effects not listed here, tell your healthcare professional.

Side effects with Taro-Diclofenac Potassium Powder for Oral Solution may include:

- Abdominal pain, nausea, vomiting, constipation, indigestion, heartburn, belching, feeling gassy or bloated
- Skin sensitivity to light, bruising, itchy skin, purple discoloured spots on the skin, hives, skin rash, redness of the skin
- Headache
- Migraine
- Difficulty sleeping
- "Pins and needles" sensation on the skin
- Feeling restless, irritable, nervous or agitated
- muscle pain
- Hair loss
- Excessive sweating
- Lack of energy or feeling weak

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Uncommon			
Gastrointestinal (GI) problems (bleeding, blockage, holes, ulcers or inflammation in your GI tract): blood in vomit, black tarry or bloody stool, dizziness, stomach pain, bloating, loss of appetite, weight loss, nausea, vomiting, constipation or diarrhea, chills or fever		✓	
Unknown			
Blood problems (low white and/or red blood cell or platelet count): feeling tired or weak, pale skin, bruising or bleeding for longer than usual if you hurt yourself, fever, chills		✓	
Congestive heart failure (heart does not pump blood as well as it should): shortness of breath, fatigue and weakness, swelling in ankles, legs and feet, cough, fluid retention, lack of appetite, nausea, rapid or irregular heartbeat, reduced ability to exercise			✓

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Myocardial infarction (heart attack): pressure or squeezing pain between the shoulder blades, in the chest, jaw, left arm or upper abdomen, shortness of breath, dizziness, fatigue, light-headedness, clammy skin, sweating, indigestion, anxiety, feeling faint and possible irregular heartbeat			✓
Stroke (bleeding or blood clot in the brain): sudden numbness, weakness or tingling of the face, arm, or leg, particularly on one side of the body, sudden headache, blurry vision, difficulty swallowing or speaking, or lethargy, dizziness, fainting, vomiting, trouble understanding, trouble with walking and loss of balance			✓
Tinnitus (hearing problems): includes ringing, buzzing, clicking or hissing in ears, loss of hearing		✓	
Vertigo (a sense of severe spinning dizziness, lightheadedness)		✓	
Liver problems: yellowing of your skin and eyes (jaundice), right upper stomach area pain or swelling, nausea or vomiting, unusual dark urine, unusual tiredness, fever, light-coloured stool		✓	
Urinary problems: increased need to urinate, pain in the pelvis or lower back, frequent urination during the night, cloudy urine that may contain blood, burning or pain urinating		✓	
Aseptic meningitis (inflammation of the protective lining of the brain that is not caused by infection): Headaches, stiff neck, nausea and vomiting, fever or clouding of consciousness		✓	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Depression (sad mood that will not go away): difficulty sleeping or sleeping too much, changes in appetite or weight, reduced sex drive and thoughts of death or suicide		✓	
Kidney problems (including kidney failure and nephritis): nausea, vomiting, fever, swelling of extremities, fatigue, thirst, dry skin, irritability, dark urine, increased or decreased urine output, blood in the urine, itchiness or rash, weight gain (from retaining fluid), loss of appetite, mental status changes (drowsiness, confusion, coma)		✓	
Lung problems, asthma: increased shortness of breath with everyday activities or at rest, wheezing, difficulty breathing, coughing and chest tightness, irregular or fast heartbeat, coughing up blood, tiredness, dizziness			✓
Serious skin reactions: fever, severe rash, swollen lymph glands, flu-like feeling, blisters and peeling skin that may start in and around the mouth, nose, eyes and genitals and spread to other areas of the body, swelling of face and/or legs, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feeling thirsty, urinating less often, less urine or dark urine, hives, red or dry itchy skin, purple or red spots on skin			✓
Anaphylaxis/hypersensitivity (severe allergic reactions): sudden wheeziness and chest pain or tightness, swelling of eyelids, face, lips, tongue or throat, swelling or anaphylactic reaction/shock			✓
Fluid retention/edema: rapid weight gain, unusual swelling of hands, ankles, feet or face		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects
You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store at room temperature 15°C to 30°C.
- **Do NOT keep outdated medicine or medicine no longer needed**.

  Any outdated or unused medicine should be returned to your pharmacist.
- Keep out of reach and sight of children.

If you want more information about Taro-Diclofenac Potassium Powder for Oral Solution:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website (www.taro.ca); or by calling 1- 800-268-1975.

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