PRESCRIBING INFORMATION

ORAL PURGATIVE

Magnesium oxide, citric acid and sodium picosulfate
Powder for oral solution

Purgative

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PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Oral	Each sachet contains: Powder : citric acid 12g; magnesium oxide 3.5 g; sodium picosulfate 10 mg	For a complete listing see the Dosage Forms, Composition and Packaging section of the Prescribing Information.

General
The active components of ORAL PURGATIVE are sodium picosulfate and magnesium citrate.

Picosulfate (a pro-drug) is a stimulant cathartic active locally in the colon.

Magnesium citrate (magnesium oxide and citric acid) acts as an osmotic laxative by retaining moisture in the colon. The action is of a powerful "washing out" effect combined with peristaltic stimulation to clear the bowel prior to radiography, colonoscopy or surgery. Full doses of the saline cathartics (15 g of magnesium sulfate or its equivalent) produces a semifluid of watery evacuation within 3-6 hours or less.

The product is not intended for routine use as a laxative.

Some absorption of the component ions of the saline cathartics does occur, and in certain instances they may produce systemic toxicity. This is especially true for magnesium salts, since 20% or more of the administered cation is absorbed. If renal function is normal, the absorbed magnesium is rapidly excreted. However, if a magnesium cation is given to an individual with impaired renal function, the accumulation of magnesium ion in the body fluids may be sufficient to cause magnesium intoxication.

In most instances, salts that gain access to the systemic circulation are rapidly excreted by the kidneys.

INDICATIONS AND CLINICAL USE

ORAL PURGATIVE is indicated for clearance of the bowel prior to x-ray examination, endoscopy or surgery.

CONTRAINDICATIONS

ORAL PURGATIVE is contraindicated in:

- Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. For a complete listing, see the DOSAGE FORMS, COMPOSITION AND PACKAGING section of this document.

- Patients with congestive cardiac failure, gastric retention, gastro-intestinal ulceration, toxic colitis, toxic megacolon, ileus, nausea and vomiting, acute surgical abdominal conditions such as acute appendicitis and known or suspected gastro-intestinal obstruction or perforation.

- Patients with severely reduced renal function, accumulation of magnesium in plasma may occur. Another preparation should be used in such cases.

WARNINGS AND PRECAUTIONS

Care should also be taken in patients with renal impairment, heart disease or inflammatory bowel disease.

Use with caution in patients on drugs that might affect water and/or electrolyte balance e.g. diuretics, corticosteroids, lithium [see *Drug Interactions and Adverse Reactions]*.

ORAL PURGATIVE may modify the absorption of regularly prescribed oral medication and should be used with caution e.g. there have been isolated reports of seizures in patients on antiepileptics, with previously controlled epilepsy [see *Drug Interactions and Adverse Reactions*].

Patients should avoid taking oral iron preparations for a week before colonoscopy. Constipating drugs (e.g. cholinergics, opioids) should be suspended for a few days before the procedure, after consulting with your doctor.

An inadequate oral intake of water and electrolytes could create clinically significant deficiencies, particularly in less fit patients. In this regard, the elderly, debilitated individuals and patients at risk of hypokalaemia may need particular attention. Prompt corrective action should be taken to restore fluid/electrolyte balance in patients with signs or symptoms of hyponatraemia.

The period of bowel cleansing should not exceed 24 hours because longer preparation time may increase the risk of water and electrolyte imbalance.

Serious Fluid and Serum Chemistry Abnormalities
Advise patients to hydrate adequately before, during and after the use of ORAL PURGATIVE. Use caution in patients with congestive heart failure when replacing fluids. If a patient develops significant vomiting or signs of dehydration including signs of orthostatic hypotension after taking ORAL PURGATIVE, consider performing post-colonoscopy lab tests (electrolytes, creatinine and BUN) and treat accordingly. Approximately 20% of patients in clinical trials had orthostatic changes (changes in blood pressure and/or heart rate) on the day of colonoscopy; however these changes were not clinically relevant. In clinical trials orthostatic changes were documented out to seven days post colonoscopy [see Adverse Reactions].

Fluid and electrolyte disturbances can lead to serious adverse events including cardiac arrhythmias or seizures and renal impairment. Fluid and electrolyte abnormalities should be corrected before treatment with ORAL PURGATIVE. In addition, use caution when prescribing ORAL PURGATIVE for patients who have conditions or who are using medications that increase the risk for fluid and electrolyte disturbances or that may increase the risk of adverse events of seizure, arrhythmia, and renal impairment.

Seizures
There have been reports of generalized tonic-clonic seizures with the use of bowel preparation products in patients with no prior history of seizures. Seizures were associated with electrolyte abnormalities (e.g. hyponatremia, hypokalemia, hypocalcemia and hypomagnesemia) and low serum osmolality. Neurologic abnormalities resolved with correction of fluid and electrolyte abnormalities.

Use caution when prescribing ORAL PURGATIVE for patients with a history of seizures and in patients at risk of seizure, such as patients taking medications that lower the seizure threshold (e.g. tricyclic antidepressants), patients withdraw from alcohol or benzodiazepines, patients with known or suspected hyponatremia. [see Adverse Reactions]

Use in Patients with Renal Impairment
As in other magnesium containing bowel preparations, use caution when prescribing ORAL PURGATIVE for patients with impaired renal function or patients taking concomitant medications that may affect renal function (such as diuretics, angiotensin converting enzyme inhibitors, angiotensin receptor blockers, or non-steroidal anti-inflammatory drugs). These patients may be at increased risk for renal injury. Advise these patients of the importance of adequate hydration before, during and after the use of ORAL PURGATIVE. Consider performing baseline and post-colonoscopy laboratory tests (electrolytes, creatinine and BUN) in these patients. In patients with severely reduced renal function (creatinine clearance < 30 mL/min), accumulation of magnesium in plasma may occur.

Cardiac Arrhythmias
There have been rare reports of serious arrhythmias associated with the use of ionic osmotic laxative products for bowel preparation. Use caution when prescribing ORAL PURGATIVE for patients at increased risk of arrhythmias (e.g. patients with a history of prolonged QT, uncontrolled arrhythmias, recent myocardial infarction, unstable angina, congestive heart failure, or cardiomyopathy).

Colonic Mucosal Ulceration, Ischemic Colitis and Ulcerative Colitis
Osmotic laxatives may produce colonic mucosal aphthous ulceration and there have been reports of more serious cases of ischemic colitis requiring hospitalization. Concurrent use of additional stimulant laxatives with ORAL PURGATIVE may increase this risk. The potential for mucosal ulceration should be considered when interpreting colonoscopy findings in patients with known or suspected inflammatory bowel disease [see Adverse Reactions].

Use in Patients with Significant Gastrointestinal Disease
If gastrointestinal obstruction or perforation is suspected, perform appropriate diagnostic studies to rule out these conditions before administering ORAL PURGATIVE. Use with caution in patients with severe active ulcerative colitis.

Aspiration
Patients with an impaired gag reflex and patients prone to regurgitation or aspiration should be observed during the administration of ORAL PURGATIVE. Use with caution in these patients.

Not for Direct Ingestion
Each packet must be dissolved in 150 mL (5 oz) of cold water and administered at separate times according to the dosing regimen. Direct ingestion of the undissolved powder may increase the risk of nausea, vomiting, dehydration, and electrolyte disturbances.

Pregnancy and Lactation
Reproduction studies with sodium picosulfate performed in animals have revealed no evidence of a harmful action on the fetus. However, clinical experience of the use of ORAL PURGATIVE during pregnancy is limited and caution should be observed, particularly during the first trimester.

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ORAL PURGATIVE is administered to a nursing woman.

Geriatrics (≥ 65 years of age)
In controlled clinical trials of bowel preparations like ORAL PURGATIVE, 215 of 1201 (18%) patients were 65 years of age or older. The overall incidence of treatment-emergent adverse events was similar among patients ≥ 65 years of age (73%) and patients < 65 years of age (71%).

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in clinical trials of another drug and may not reflect the rates observed in practice.

In randomized, multicenter, controlled clinical trials, nausea, headache and vomiting were the most common adverse reactions (>1%) following administration of bowel preparations like ORAL PURGATIVE. The patients were not blinded to the study drug. Since abdominal bloating, distension, pain/cramping and watery diarrhea are known to occur in response to colon cleansing preparations, these effects were documented as adverse events in the clinical trials only if they required medical intervention (such as a change in study drug or led to study discontinuation, therapeutic or diagnostic procedures, met the criteria for a serious adverse event), or showed clinically significant worsening during the study that was not in the frame of the usual clinical course, as determined by the investigator.

Post-marketing Experience

The following spontaneous reports have been identified during use of formulations similar to ORAL PURGATIVE. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Allergic reactions

Cases of hypersensitivity reactions including rash, urticaria and purpura have been reported.

Electrolyte abnormalities

There have been reports of hypokalemia, hyponatremia and hypermagnesemia with the use of bowel preparations similar to ORAL PURGATIVE for colon preparation prior to colonoscopy.

Gastrointestinal

Abdominal pain, diarrhea, fecal incontinence and proctalgia have been reported with the use of bowel preparations similar to ORAL PURGATIVE for colon preparation prior to colonoscopy. There have been isolated reports of reversible aphthoid ileal ulcers. Ischemic colitis has been reported with the use of bowel preparations similar to ORAL PURGATIVE for colon preparation prior to colonoscopy. However, a causal relationship between these ischemic colitis cases and the use of bowel preparations similar to ORAL PURGATIVE has not been established.

Neurologic

There have been reports of generalized tonic-clonic seizures associated with and without hyponatremia in epileptic patients.

DRUG INTERACTIONS

As a purgative, ORAL PURGATIVE increases the gastrointestinal transit rate therefore the absorption of other orally administered medicines (e.g. anti-epileptics, contraceptives, antidiabetics, antibiotics) may be modified during the treatment period (see *Warnings and Precautions for Use*).

The efficacy of ORAL PURGATIVE is lowered by bulk-forming laxatives.

Drugs That May Increase Risks of Fluid and Electrolyte Abnormalities
Use caution when prescribing ORAL PURGATIVE for patients with conditions or who are using medications that increase the risk for fluid and electrolyte disturbances, or may increase the risk of seizure, arrhythmias, and prolonged QT in the setting of fluid and electrolyte abnormalities. This includes patients receiving drugs which may be associated with hypokalemia (such as diuretics or corticosteroids, or drugs where hypokalemia is a particular risk, such as cardiac glycosides) or hyponatremia. Use caution when ORAL PURGATIVE is used in patients on non-steroidal anti-inflammatory drugs (NSAIDS) or drugs known to induce Antidiuretic Hormone Secretion (SIADH), such as tricyclic antidepressants, selective serotonin re-uptake inhibitors, antipsychotic drugs and carbamazepine, as these drugs may increase the risk of water retention and/or electrolyte imbalance. Consider additional patient evaluations as appropriate *[see Adverse Reactions]*.

Potential for Altered Drug Absorption
Oral medication administered within one hour of the start of administration of ORAL PURGATIVE solution may be flushed from the GI tract and the medication may not be absorbed.

Tetracycline and fluoroquinolone antibiotics, digoxin, chlorpromazine and penicillamine, should be taken at least 2 hours before and not less than 6 hours after administration of ORAL PURGATIVE to avoid chelation with magnesium.

DOSAGE AND ADMINISTRATION

PRE-DOSING INSTRUCTIONS:

- **At least 3 days prior to the patients procedure, advise the patient to not** consume seeds or nuts due to digestive residue or fresh fruits or raw vegetables (i.e. no salads) and no multigrain bread

ADULT DOSING INSTRUCTIONS: Fill a mug with 150 ml (5 oz) of cold water. Empty contents of one sachet in the mug (rarely, mixture may heat up - allow to cool before drinking). Stir until completely dissolved. **Following each sachet dose, advise the patient to drink 1.5 to 2 Litres of a variety of clear fluids over 4 hours. Advise the patient TO NOT DRINK JUST WATER ALONE.** Patients should also drink a balanced electrolyte solution. Drinking only water to replace the fluid losses may lead to electrolyte imbalance, particularly to hyponatremia

and possibly seizures. A good option is to also drink a balanced-electrolyte solution as recommended by a health professional to replace fluid losses.

Recommended clear fluids include Gatorade†, fruit juices, clear both, tea or coffee (black, sweetened to taste, **no** milk, cream or soy), clear sodas (e.g. ginger ale), plain Jell-O† (not red or purple), Popsicles† (not red or purple) and water.

Diabetics can use a fibre-free supplement/meal replacement.

Two doses are normally taken 6 to 8 hours apart on the day before the hospital procedure. Drink plenty of clear fluids during use.

Adults: Mix and dissolve the contents of one sachet in a cup of cold water. Stir for 2-3 minutes and drink the solution. If it becomes hot, wait until it cools before you drink it.

First dose: 1 sachet before 8 am on the day before the procedure.

Second dose: 1 sachet between 2 pm and 4 pm on the day before the procedure.

No fluid should be taken at least 2 hours prior to the procedure.

PEDIATRIC DOSING INSTRUCTIONS:

Fill a mug with 150 ml (5 oz) of cold water. Empty contents of one sachet in the mug (rarely, mixture may heat up - allow to cool before drinking). Stir until completely dissolved.

It is recommended that ORAL PURGATIVE should be given at least 5-6 hours before bedtime to avoid interference with sleep. The sachet should be taken according to the recommendations below:

Children (1 to 6 years old) ¼ sachet morning, ¼ sachet afternoon.

Children (6 to 12 years old) ½ sachet morning, ½ sachet afternoon.

In general patients should drink about 250 mL of clear fluids **and/or a balanced electrolytes solution as recommended by a health care professional,** every hour while they feel the effects of ORAL PURGATIVE.

No fluid should be taken at least 2 hours prior to the procedure

OVERDOSAGE

For management of a suspected drug overdose, contact your regional Poison Control Centre.

† All other trademarks are the property of their respective owners

STORAGE AND STABILITY

Store at 15 °C - 25 °C.

Keep out of the reach of children.

DOSAGE FORMS, COMPOSITION AND PACKAGING

ORAL PURGATIVE is supplied in sachet containing sodium picosulfate 10 mg, magnesium oxide 3.5 g and citric acid 12g. Non-medicinal ingredients: orange flavor, potassium bicarbonate and sodium saccharin. Cartons of 1or 2 sachets.

PART II: CONSUMER INFORMATION

ORAL PURGATIVE

Magnesium oxide, citric acid and sodium picosulfate
Powder for oral solution

Purgative

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ORAL PURGATIVE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

ORAL PURGATIVE is a white powder. It is a very strong purgative (i.e. to empty bowels). ORAL PURGATIVE is used to cleanse the bowel of faecal matter and secretions prior to x-ray examination, endoscopy or surgery. This product is not intended for routine use as a laxative.

When it should not be used:
1. If you are allergic to any of the ingredients (see above).
2. If you have any of the following; gastric retention (reduced ability of the stomach to empty), gastric or intestinal ulcers, appendicitis, gastrointestinal blockage or perforation.
3. If you have ileus (intestinal blockage or failure of normal movements), toxic colitis (damage to intestinal wall) or toxic megacolon (acute dilatation of the large bowel). In these conditions, transit of the contents of the bowel may be impaired or prevented. Symptoms include nausea, vomiting, diarrhoea, abdominal pain, tenderness or swelling, colicky pain and fever.
4. If you have congestive cardiac failure (the heart is unable to pump blood efficiently around the body).
5. If you have severely reduced kidney function.

What it does:
Magnesium oxide and citric acid combine together (chemical reaction) in water to form magnesium citrate, which works as an osmotic laxative drawing water into the bowel to help make the stool soft and more watery. Sodium picosulfate works as a stimulant laxative to increase the bowel movements to move- the contents along. Together they work to empty the bowel prior to medical procedures.

What the medicinal ingredient is:
Each sachet contains 16.1 g of powder which has three active ingredients: sodium picosulfate 10 mg, magnesium oxide 3.5g and citric acid 12 g;, the later two form magnesium citrate in solution.

What the important nonmedicinal ingredients are:

Orange flavor, potassium bicarbonate and sodium saccharin.

What dosage forms it comes in:
Powder

WARNINGS AND PRECAUTIONS

Please consult your doctor before taking ORAL PURGATIVE if you:

- Have recently had gastrointestinal surgery,
- Have a medical condition affecting the heart or kidneys,
- Have inflammatory bowel disease such as ulcerative colitis or Crohn's disease,
- Are using bulk forming laxatives e.g. bran.
- Have heart problems such as a recent heart attack, irregular or fast heartbeat (arrhythmia), lengthened heart beat (QT prolongation) or angina
- Have a history of seizures
- Have an impaired gag reflex

Pregnancy or Breast-Feeding: If you are pregnant or are breast-feeding, ask your doctor or pharmacist for advice before taking ORAL PURGATIVE.

INTERACTIONS WITH THIS MEDICATION

Taking Other Medicines:
Please inform your doctor or pharmacist:

- If you are taking or have recently taken or used any other medicines – even those that are available without a prescription.
- If you are taking anti-epileptics, contraceptives, antibiotics, diabetes medications and cardiac glycosides as they may be affected during treatment with Oral Purgative.
- If you are taking diuretics, corticosteroids and lithium as these drugs may affect electrolyte balance.
- If you are taking nonsteroidal anti-inflammatory drugs (NSAIDS), tricyclic antidepressants, antipsychotic drugs or carbamazapine as these drugs may add to the electrolyte imbalance.
- If you are taking oral iron preparations for a week before colonoscopy.
- If you are taking constipating drugs (e.g. cholinergics, opioids); they should be temporarily discontinued for a few days before the procedure.
- If you are taking Tetracycline and fluoroquinolone antibiotics, digoxin, chlorpromazine and penicillamine they should be taken 2 hours before or not less than 6 hours after taking ORAL PURGATIVE, to avoid loss of effectiveness of these other medications

If you have special dietary requirements, please discuss this with your doctor.

PROPER USE OF THIS MEDICATION

At least 3 days prior to your procedure:

- Do not consume seeds or nuts due to digestive residue
- Do not consume any fresh fruits or raw vegetables (i.e. no salads) and no multigrain bread

ADULT DOSING INSTRUCTIONS:
Fill a mug with 150 ml (5 oz) of cold water. Empty contents of one sachet in the mug (rarely, mixture may heat up - allow to cool before drinking). Stir for 2-3 minutes until completely dissolved before you drink. **Following each sachet, drink 1.5 to 2 Litres of a variety of clear fluids over 4 hours.**

DO NOT DRINK JUST WATER ALONE. Drinking only water to replace the fluid losses may lead to electrolyte imbalance, particularly to hyponatremia and possibly seizures. A good option is to also drink a balanced electrolyte solution (e.g. Gastrolyte†, Pedialyte†) as recommended by a health professional to replace fluid losses.

Recommended clear fluids include any fluid that you **can see through,** that is **not red or purple**; such as sports drinks (e.g. Gatorade†), Gastrolyte†, Pedialyte†, Kool-Aid†, clear broth (chicken, vegetable or beef stock with no noodles, meat or vegetables), fruit juices (e.g. apple, white (not red) cranberry, white (not purple) grape), tea or coffee (black, sweetened to taste, **no** milk, cream or soy), clear sodas (e.g. ginger ale), plain Jell-O† (not red or purple), Popsicles† (not red or purple) and water.

Diabetics can use a fibre-free supplement/meal replacement.

One day before your procedure you should have **clear fluids ONLY and no solid food.**

Two doses are normally taken 6 to 8 hours apart on the day before the hospital procedure. Drink plenty of clear fluids during use.

Adults: Mix and dissolve the contents of one sachet in a cup of cold water. Stir for 2-3 minutes and drink the solution. If it becomes hot, wait until it cools before you drink it.

First dose: 1 sachet before 8 am on the day before the procedure.

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No fluid should be taken at least 2 hours prior to the procedure.

PEDIATRIC DOSING INSTRUCTIONS:

Fill a mug with 150 ml (5 oz) of cold water. Empty contents of one sachet in the mug (rarely, mixture may heat up - allow to cool before drinking). Stir until completely dissolved.

It is recommended that ORAL PURGATIVE should be given at least 5-6 hours before bedtime to avoid interference with sleep. The sachet should be taken according to the recommendations below:

Children (1 to 6 years old) ¼ sachet morning, ¼ sachet afternoon.

Children (6 to 12 years old) ½ sachet morning, ½ sachet afternoon.

In general patients should drink about 250 mL of clear fluids **and/or a balanced electrolytes solution as recommended by a health care professional,** every hour while they feel the effects of ORAL PURGATIVE.

No fluid should be taken at least 2 hours prior to the procedure.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, ORAL PURGATIVE can cause side effects, although not everybody gets them. Adverse reactions to ORAL PURGATIVE are very rare (< 1 in 10, 000). Some examples include: hyponatraemia, epilepsy, grand mal convulsions, nausea, rash, headache, anaphylactoid reaction, hypersensitivity.

If any side effects become serious or persist, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	Hyponatraemia is a metabolic condition in which there is not enough sodium (salt) in the body fluids outside the cells, Symptoms can include vomiting, confusion, fatigue and irritability		√	√
	Convulsion, epilepsy, confusional state, headache.		√	√
	Vomiting, diarrhea, abdominal pain, nausea		√	

This is not a complete list of side effects. For any unexpected effects while taking ORAL PURGATIVE contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature (15°C to 25°C).

Keep out of reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789, or**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 0701D
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting Odan Laboratories Ltd. at 1-866-666-ODAN.

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