

PRESCRIBING INFORMATION

PicoFLO™

Magnesium Oxide, Citric Acid and Sodium Picosulfate
Powder for Oral Solution
3.5 g, 12 g and 10 mg per sachet

Purgative

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PicoFLO™

Magnesium Oxide, Citric Acid and Sodium Picosulfate
Powder for Oral Solution
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HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Non-medical Ingredients
Oral	Each sachet contains: Powder for oral solution: magnesium oxide 3.5 g; citric acid 12 g; sodium picosulfate 10 mg	<i>None.</i> <i>For a complete listing see Dosage Forms, Composition and Packaging section.</i>

General

The active components of PicoFLO (Magnesium Oxide, Citric Acid, Sodium Picosulfate Powder for Oral Solution) are magnesium citrate and sodium picosulfate. Magnesium citrate (magnesium oxide and citric acid) acts as an osmotic laxative by retaining moisture in the colon. Picosulfate (a pro-drug) is a stimulant cathartic active locally 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 semi-fluid 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

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

CONTRAINDICATIONS

PicoFLO is contraindicated for use 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.
- with a known or suspected acute surgical abdominal conditions such as acute appendicitis and known or suspected gastrointestinal obstruction or perforation.
- with congestive cardiac failure
- with gastric retention, gastrointestinal ulceration, toxic colitis, toxic megacolon, ileus, nausea and/or vomiting.
- with severely reduced renal function, accumulation of magnesium in plasma may occur. Another preparation should be used in such cases.

WARNINGS AND PRECAUTIONS

General

Care should be taken for patients who recently had gastrointestinal surgery, as well as for 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* sections).

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

PicoFLO may modify the absorption of regularly prescribed oral medication and should be used with caution. There have been isolated reports of seizures in patients on antiepileptics, with previously controlled epilepsy after taking sodium picosulfate and magnesium citrate preparations (see *Drug Interactions* and *Adverse Reactions* sections).

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 PicoFLO. 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 PicoFLO, consider performing post-colonoscopy laboratory tests (electrolytes, creatinine and BUN) and treat accordingly. Approximately 20% of patients in clinical trials using sodium picosulfate/magnesium citrate preparations 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 up to seven days post-colonoscopy (see *Adverse Reactions* section).

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 PicoFLO. In addition, use caution when prescribing PicoFLO 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 PicoFLO 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* section).

Use in Patients with Renal Impairment

As in other magnesium containing bowel preparations, use caution when prescribing PicoFLO 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 PicoFLO. 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 PicoFLO 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 PicoFLO 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* section).

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 PicoFLO. 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 PicoFLO. Use with caution in these patients.

Not for Direct Ingestion

Each sachet 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.

Special Populations

Pregnant Women:

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 PicoFLO during pregnancy is limited and caution should be observed, particularly during the first trimester.

Nursing Women:

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 PicoFLO is administered to a nursing woman.

Geriatrics (≥ 65 years of age)

In controlled clinical trials using sodium picosulfate and magnesium citrate combination products, 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 Adverse Drug Reactions

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 sodium picosulfate/magnesium citrate preparations. 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 which led to study discontinuation, therapeutic or diagnostic procedures or which 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-Market Adverse Drug Reactions

The following spontaneous reports have been identified during use of formulations similar to PicoFLO. 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 sodium picosulfate, citric acid and magnesium oxide combination products used for colon preparation prior to colonoscopy.

Gastrointestinal

Abdominal pain, diarrhea, fecal incontinence and proctalgia have been reported with the use of sodium picosulfate, citric acid and magnesium oxide combination products used 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 sodium picosulfate, citric acid and magnesium oxide combination products used for colon preparation prior to colonoscopy. However, a causal relationship between these ischemic colitis cases and the use of the sodium picosulfate, citric acid and magnesium oxide combination products has not been established.

Neurologic

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

DRUG INTERACTIONS

Drug-Drug Interactions

As a purgative, PicoFLO increases the gastrointestinal transit rate. The absorption of other orally administered medicines (e.g., anti-epileptics, contraceptives, anti-diabetics, antibiotics) may therefore be modified during the treatment period (see *Warnings and Precautions* section). A purgative should not be taken within 2 hours of another medicine because the desired effect of the other medicine may be reduced.

The efficacy of PicoFLO is lowered by bulk-forming laxatives.

Drugs That May Increase Risks of Fluid and Electrolyte Abnormalities

Use caution when prescribing PicoFLO 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 PicoFLO is used in patients on non-steroidal anti-inflammatory drugs (NSAIDs) or drugs known to induce the Syndrome of Inappropriate 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* section).

Potential for Altered Drug Absorption

Oral medication administered within one hour of the start of administration of PicoFLO 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 PicoFLO to avoid chelation with magnesium.

DOSAGE AND ADMINISTRATION

PRE-DOSING INSTRUCTIONS:

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

On the day before the procedure the patient should have ONLY clear fluids and NO solid food.

ADULT DOSING INSTRUCTIONS:

Preparation and Administration of the Product

For bowel cleansing, two sachets of the product are used and dosed at two separate times as defined in the subsection *Dosing Schedule* below.

To prepare each dose of the product, mix the entire powder contents of one sachet with 150 mL or 5 oz of cold water in a cup; stir until the powder is completely dissolved. This may take 2-3 minutes. If the solution becomes hot, let it cool down before drinking it.

Following each dose, advise the patient to drink 1.5 to 2 Liters of a variety of clear fluids over the next 4 hours. Advise the patient NOT TO DRINK ONLY WATER. Patients should also drink a balanced electrolyte solution (e.g., Electrolyte Gastro^{*}, Gastrolyte^{*}).

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 broth, tea or coffee (black, sweetened to taste, **without** added 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.

Dosing Schedule:

There are two different dosing schedules for the two doses of the product based on the intended time for colonoscopy examination as described below.

- **MORNING COLONOSCOPY:** For patients with colonoscopy examination scheduled at a time before 12:00 pm (noon), the following dosing schedule should be followed. Such dosing schedule is also called “**day-before dosing**” since the two doses are administered on the same day before the procedure.

One day BEFORE the procedure:

- 1- Take **1 sachet** (first dose) in the afternoon or early evening (around 5:00 pm) followed by 6 to 8 cups (250 mL or 8 oz each) of a variety of clear fluids as described above.
- 2- Take **1 sachet** (second dose) in the late evening (around 10:00 pm) followed by 6 to 8 cups (250 mL or 8 oz each) of a variety of clear fluids as described above.

No fluids should be ingested at least 2 hours prior to the procedure.

- **AFTERNOON COLONOSCOPY:** For patients with colonoscopy examination scheduled at 12:00 pm (noon) or later, the following dosing schedule should be followed. Such dosing schedule is also called “**split-dose dosing**” since the two doses are administered on separate days.

1- One day BEFORE the procedure: Take **1 sachet** (first dose) in the evening (around 7:00 pm) followed by 6 to 8 cups (250 mL or 8 oz each) of a variety of clear fluids as described above.

2- On the SAME DAY as the procedure: Take **1 sachet** (second dose) in the early morning (around 6:00 am), followed by 6 to 8 cups (250 mL or 8 oz each) of a variety of clear fluids as described above.

No fluids should be ingested at least 2 hours prior to the procedure.

In order to replace fluid lost from the body, advise patients to drink plenty of clear fluids throughout the treatment with PicoFLO until bowel movements have ceased.

PEDIATRIC DOSING INSTRUCTIONS:

Preparation and Administration of the Product

Mix the entire powder contents of one sachet with 150 mL or 5 oz of cold water in a cup; stir until the powder is completely dissolved. This may take 2-3 minutes. If the solution becomes hot, let it cool down before drinking it.

It is recommended that PicoFLO be given to the child at least 5 to 6 hours before bedtime to avoid interference with sleep. Splitting the two doses over two days is recommended as described below:

Dosing Schedule:

Children (1 to 6 years old):

- 1- One day BEFORE the procedure:** Give the child $\frac{1}{4}$ of the prepared solution (first dose) as per DOSING INSTRUCTIONS in the evening (around 6:00 pm), followed by 1 cup (250 mL or 8 oz) of a variety of clear fluids as described above every hour while the child is awake.
No solid food should be ingested after 6:00 pm.
- 2- On the SAME DAY as the procedure:** Give the child $\frac{1}{4}$ of the prepared solution (second dose) as per DOSING INSTRUCTIONS in the morning (around 8:00 am), followed by 1 cup (250 mL or 8 oz) of a variety of clear fluids as described above every hour, up to 2 hours prior to the child's procedure.

No fluids should be ingested at least 2 hours prior to the procedure.

Children (6-12 years old):

- 1- One day BEFORE the procedure:** Give the child $\frac{1}{2}$ of the prepared solution (first dose) as per DOSING INSTRUCTIONS in the evening (around 6:00 pm), followed by 1 cup (250 mL or 8 oz) of a variety of clear fluids as described above every hour while the child is awake.
No solid food should be ingested after 6:00 pm.
- 2- On the SAME DAY as the procedure:** Give the child $\frac{1}{2}$ of the prepared solution (second dose) as per DOSING INSTRUCTIONS in the morning (around 8:00 am), followed by 1 cup (250 mL or 8 oz) of a variety of clear fluids as described above every hour, up to 2 hours prior to the child's procedure.

No fluids should be ingested at least 2 hours prior to the procedure.

In order to replace fluids lost from the body, it is important to drink plenty of clear fluids throughout the treatment with PicoFLO until the bowel movements have ceased. In general, patients should drink about 250 mL (8 oz) of clear fluids **and/or a balanced electrolytes solution** (e.g., Electrolyte Gastro^{*}, Pediatric Electrolyte^{*}, Gastrolyte^{*}, Pedialyte^{*}) as recommended by a health professional, every hour while they feel the effects of PicoFLO.

OVERDOSAGE

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

ACTION AND CLINICAL PHARMACOLOGY

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 semi-fluid of watery evacuation within 3-6 hours or less.

Sodium picosulfate is a stimulant cathartic active locally in the colon.

The product is not intended for use as a routine 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.

STORAGE AND STABILITY

Store the package between 15°C and 30°C.
Keep out of reach of children.

DOSAGE FORMS, COMPOSITION AND PACKAGING

PicoFLO is supplied in a carton containing 2 sachets, each holding 16.1 grams of powder for oral solution. Each sachet contains 3.5 g magnesium oxide, 12 g citric acid, and 10 mg sodium picosulfate. The excipients include potassium bicarbonate, sodium saccharin, and orange flavour.

CONSUMER INFORMATION

PicoFLO™

Magnesium Oxide, Citric Acid and Sodium Picosulfate Powder for Oral Solution Purgative

This leaflet is part of the Prescribing Information published when PicoFLO was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PicoFLO. Contact your doctor or pharmacist if you have any questions about the drug.

READ ALL OF THIS INFORMATION CAREFULLY BEFORE YOU START USING THIS MEDICINE

- If your doctor's preparation instructions differ from the instructions given below, please follow your doctor's instructions. The preparation instructions presented here are only a guide and your doctor may have more specific instructions.
- Keep this insert as you may need to use it again.
- This medicine is for **your use only** and you should not give it to others.

ABOUT THIS MEDICATION

What the medication is used for:

PicoFLO is a white powder. It is a very strong purgative (i.e. to empty bowels). PicoFLO 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.

What it does:

Magnesium oxide and citric acid combine together in water (chemical reaction) to form magnesium citrate, which works as an osmotic laxative by 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.

When it should not be used:

Do not use PicoFLO if:

- You are allergic to sodium picosulfate, magnesium oxide, citric acid, or to any of the non-medicinal ingredients.
- You have any of the following: gastric retention (reduced ability of the stomach to empty), gastric or intestinal ulcers, appendicitis, gastrointestinal blockage or perforation.
- 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.

- You have congestive cardiac failure (the heart is unable to pump blood efficiently around the body).
- You have severely reduced kidney function.

What the medicinal ingredients are:

Each 16.1 g sachet of PicoFLO contains: 3.5 g magnesium oxide, 12 g citric acid and 10 mg sodium picosulfate; the first two ingredients react and produce magnesium citrate in solution.

What the important non-medicinal ingredients are:

Orange flavour, potassium bicarbonate and saccharin sodium.

What dosage forms it comes in:

PicoFLO is available as a powder to be dissolved in 150 mL (5 oz) of cold water. Each carton contains 2 sachets.

WARNINGS AND PRECAUTIONS

BEFORE you use PicoFLO talk to your doctor or pharmacist if:

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

INTERACTIONS WITH THIS MEDICATION

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.
- You are taking anti-epileptics, contraceptives, antibiotics, diabetes medications or cardiac glycosides as they may be affected during treatment with PicoFLO.
- You are taking diuretics, corticosteroids or lithium as these drugs may affect electrolyte balance.

- You are taking nonsteroidal anti-inflammatory drugs (NSAIDs), tricyclic antidepressants, antipsychotic drugs or carbamazepine as these drugs may add to the electrolyte imbalance.
- You are taking oral iron preparations in the week before your colonoscopy.
- You are taking constipating drugs (i.e. cholinergics, opioids), they should be suspended for few days before the procedure.
- You are taking tetracycline and fluoroquinolone antibiotics, digoxin, chlorpromazine or penicillamine they should be taken 2 hours before or not less than 6 hours after taking PicoFLO, to avoid loss of effectiveness of these other medications.

PROPER USE OF THIS MEDICATION

PRE-DOSING INSTRUCTIONS:

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

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

Your doctor will inform you of the dose that you should take. **It is important to drink a large glass (250 mL or 8 oz) of clear fluid at one hour intervals during the use of PicoFLO. Unless otherwise directed by your doctor, please follow the directions below.**

On the day before your procedure you should have **ONLY clear fluids** and **NO solid food**.

ADULT DOSING INSTRUCTIONS:

To prepare each dose of the product, mix the entire powder contents of one sachet with 150 mL or 5 oz of cold water in a cup; stir until the powder is completely dissolved. This may take 2-3 minutes. If the solution becomes hot, let it cool down before drinking it. **Following each dose, drink 1.5 to 2 Liters of a variety of clear fluids over 4 hours.**

DO NOT DRINK ONLY WATER. You should also drink a balanced electrolyte solution (e.g., Electrolyte Gastro^{*}, Gastrolyte^{*}).

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 any fluid that you **can see through**, that is **not red or purple**, such as sports drinks (e.g.,

Gatorade^{*}), fruit juices (e.g., apple, white (not red) cranberry, white (not purple) grape), balanced electrolytes solutions (e.g., Electrolyte Gastro^{*}, Gastrolyte^{*}), clear broth (chicken, vegetable or beef stock with no noodles, meat or vegetables), tea or coffee (black, sweetened to taste, **without** milk, cream or soy), clear sodas (e.g., ginger ale), Kool-Aid^{*} (not red or purple), plain Jell-O^{*} (not red or purple), Popsicles^{*} (not red or purple), and water.

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

MORNING COLONOSCOPY: before 12:00 pm (noon)

One day BEFORE your procedure:

1-Take 1 sachet (first dose) in the afternoon or early evening (around 5:00 pm) followed by 6 to 8 cups (250 mL or 8 oz each) of a variety of clear fluids as described above.

2-Take 1 sachet (second dose) in the late evening (around 10:00 pm) followed by 6 to 8 cups (250 mL or 8 oz each) of a variety of clear fluids as described above.

No fluid should be ingested at least 2 hours prior to your procedure.

AFTERNOON COLONOSCOPY: 12:00 pm (noon) or later

1-One day BEFORE your procedure: Take 1 sachet (first dose) in the evening (around 7:00 pm) followed by 6 to 8 cups (250 mL or 8 oz each) of a variety of clear fluids as described above.

2-On the SAME DAY as your procedure: Take 1 sachet (second dose) in the early morning (around 6:00 am), followed by 6 to 8 cups (250 mL or 8 oz each) of a variety of clear fluids as described above.

No fluid should be ingested at least 2 hours prior to your procedure.

In order to replace fluid lost from the body, it is important to drink plenty of clear fluids throughout the treatment with PicoFLO until bowel movements have ceased.

PEDIATRIC DOSING INSTRUCTIONS:

Mix the entire powder contents of one sachet with 150 mL or 5 oz of cold water in a cup; stir until the powder is completely dissolved. This may take 2- 3 minutes. If the solution becomes hot, let it cool down before drinking it.

It is recommended that PicoFLO be given to the child at least 5 to 6 hours before bedtime to avoid interference with sleep. Splitting the two doses over two days is recommended as described below:

Children (1 to 6 years old):

1-One day BEFORE the procedure: Give the child ¼ of the prepared solution (first dose) as per DOSING INSTRUCTIONS in the evening (around 6:00 pm), followed by 1 cup (250 mL or

8 oz) of a variety of clear fluids as described above, every hour while the child is awake.

No solid food should be ingested after 6:00 pm.

2-On the SAME DAY as the procedure: Give the child ¼ of the prepared solution (second dose) as per DOSING INSTRUCTIONS in the morning (around 8:00 am), followed by 1 cup (250 mL or 8 oz) of a variety of clear fluids as described above, every hour, up to 2 hours prior to the child’s procedure.

No fluids should be ingested at least 2 hours prior to the procedure.

Children (6-12 years old):

1-One day BEFORE the procedure: Give the child ½ of the prepared solution (first dose) as per DOSING INSTRUCTIONS in the evening (around 6:00 pm), followed by 1 cup (250 mL or 8 oz) of a variety of clear fluids as described above, every hour while the child is awake.
No solid food should be ingested after 6:00 pm.

2-On the SAME DAY as the procedure: Give the child ½ of the prepared solution (second dose) as per DOSING INSTRUCTIONS in the morning (around 8:00 am), followed by 1 cup (250 mL or 8 oz) of a variety of clear fluids as described above, every hour, up to 2 hours prior to the child’s procedure.

No fluids should be ingested at least 2 hours prior to the procedure.

In order to replace fluids lost from the body, it is important to drink plenty of clear fluids throughout the treatment with PicoFLO until the bowel movements have ceased. In general, patients should drink about 250 mL (8 oz) of clear fluids and/or a balanced electrolytes solution (e.g., Electrolyte Gastro*, Pediatric Electrolyte*, Gastrolyte*, Pedialyte*) as recommended by a health professional, every hour while they feel the effects of PicoFLO.

You should expect loose bowel movements to start at any time after taking a dose of PicoFLO. Please ensure that you have access to a toilet at all times following each dose, until the effects wear off.

The success of the procedure that you will undergo depends on the bowel being as clear as possible. The procedure may need to be repeated if you do not achieve a clear bowel. Your doctor or clinic may issue a preparation sheet with more detailed instructions, including meals or food/fluid intake, which you will be asked to follow. **Please follow your doctor’s instructions.**

The period of bowel cleansing should not exceed 24 hours because longer preparations may increase the risk of water and electrolyte imbalance. That is, you should not take more

than two sachets of PicoFLO and these are to be taken at the indicated times on the day before you are to go to the hospital for your diagnostic procedure or for surgery.

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.

Missed Dose:

If you forget to take PicoFLO, tell your doctor.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, PicoFLO can cause side effects, although not everybody gets them. Adverse reactions to PicoFLO 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 PicoFLO contact your doctor or pharmacist.

HOW TO STORE IT

Keep PicoFLO out of reach of children. Store the package between 15°C-30°C.

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 0701E
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 Prescribing Information, prepared for health professionals, can be obtained by contacting the sponsor, Pharmascience Inc. at 1-888-550-6060.

This leaflet was prepared by Pharmascience Inc.

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