1.3.1 South African Package Insert

Scheduling status:
Schedule 3
Proprietary name (and dosage form):
Colo-Prep®
powder for solution
Composition:
Each sachet contains Monobasic Sodium Phosphate anhydrous 15 g and
Dibasic Sodium Phosphate anhydrous 10 g.
Pharmacological classification:
A11.5 Medicines acting on the gastrointestinal tract: Laxatives.
Pharmacological action:
Colo-Prep is a saline laxative that acts by its osmotic properties, thus increasing stimulation of fluid secretion, thereby promoting bowel movements.
Indications:
Colo-Prep is indicated for pre-operative, pre-radiological and pre-endoscopic bowel evacuation.
Contra-indications:
Hypersensitivity to any of the ingredients.
The use of Colo-Prep is contra-indicated when the following medical problems exist: Appendicitis or symptoms of appendicitis, undiagnosed rectal bleeding, congestive heart failure, hypertension, diabetes mellitus, intestinal obstruction, hypersensitivity to oral saline laxatives, dehydration, renal function impairment, colostomy or ileostomy.
The use of Colo-Prep is contra-indicated if the patient is taking any of the following medications: Potassium-sparing diuretics or potassium supplements.
Colo-Prep is contra-indicated for use during pregnancy as it may promote sodium retention with resultant oedema.
Colo-Prep should not be given to children under the age of five years unless prescribed by a physician. Children are not usually able to describe their symptoms precisely and proper diagnosis should precede the use of a laxative.
Colo-Prep should not be administered to patients with severely impaired renal function or hyperphosphataemia. Do not use in patients with megacolon, as hypernatremic dehydration may occur.

Warnings:

It is imperative to use Colo-Prep according to the regimen under **Dosage and directions for use**, as indicated (AM/PM split dose) and that the prescribed amount of fluids is taken. See Timeline below.
There have been rare, but serious reports of acute phosphate nephropathy in patients who received oral sodium phosphate products for colon cleansing prior to colonoscopy. Some cases have resulted in permanent impairment of renal function and some patients required long–term dialysis. While some cases have occurred in patients without identifiable risk factors, patients at increased risk of acute phosphate nephropathy may include those with increased age, hypovolemia, increased bowel transit time (such as bowel obstruction), active colitis, or baseline kidney disease, and those using medicines that affect renal perfusion or function (such as diuretics, angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), and possibly nonsteroidal anti–inflammatory drugs (NSAIDs)).

Rare cases of acute phosphate nephropathy have been reported when tablet formulations similar to Colo-Prep were used, presumably as a result of inadequate hydration. It is imperative that the patient drinks the quantities of fluids mentioned in the dosage guidelines below, i.e. at least 1 glass (250 ml) every hour.
If the patient is on a low salt diet, has kidney disease, or suffers from high blood pressure, do not use this product except if the patient is under the supervision of a doctor.
Do not use when nausea, vomiting or abdominal pain is present. Frequent or prolonged use of this preparation may result in dependence on laxatives and loss of normal bowel function.

No laxative should be used for longer than one week except on advice of a doctor. If there is a sudden change in bowel habits that persists for a period greater than 2 weeks, consult a doctor before using the laxative. The product should not be used unless directed by a doctor.
Rectal bleeding or failure to have a bowel movement after use of a laxative may indicate a serious condition. Discontinue use if necessary.

Dosage and directions for use:

This product generally produces bowel movement within half an hour to six hours. Add contents of one sachet to 50 ml lukewarm water, stir and add 200 ml cool water, stir until dissolved.
Take the contents of one sachet (dissolved as indicated) orally at 17h00 the afternoon before the procedure and the contents of the next sachet (dissolved as indicated) orally the same morning of the procedure.
To keep the patient hydrated, at least 1 glass of clear liquid (250 ml) should be taken every hour.
See patient instructions under Timeline below.
Not recommended for use in children under 5 years of age.

Side-effects and special precautions:

Electrolyte imbalance that presents as confusion, irregular heartbeat, muscle cramps, unusual tiredness or weakness. The patient should consult a doctor if any of the above occurs. Cramping, diarrhoea, gas formation, nausea, vomiting and increased thirst may occur and medical attention is required only if symptoms continue or are bothersome.

Known symptoms of overdosage and particulars of its treatment.

Electrolyte imbalance that occurs as confusion, irregular heartbeat, muscle cramps, unusual tiredness or weakness. Cramping, diarrhoea, gas formation, nausea, vomiting and increased thirst may occur and medical attention is required only if symptoms continue or are bothersome.

Identification:

A fine, off-white powder with an orange taste and odour.

Presentation:

Two sachets, each containing 25,22 g powder for solution.

Storage instructions:

Store below 25 °C in a dry place. **KEEP OUT OF REACH OF CHILDREN**.

Registration number:

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