120 x 230 (F&B)

Klearit

POLYETHYLENE GLYCOL 3350 AND ELECTROLYTES FOR ORAL SOLUTION USP

PRESENTATION AND FORM
Powder for Oral solution. Box of 1 sachet

COMPOSITION :
Each pack (137.15gm) contains:

Polyethylene Glycol	USP	118.0 gm
Sodium Chloride	USP	2.93 gm
Potassium Chloride	USP	1.484 gm
Sodium Bicarbonate	USP	3.370 gm
Anhydrous Sodium Sulfate	USP	11.360 gm

THERAPEUTIC INDICATIONS
For colonic lavage prior to:
- Endoscopic and radiological examinations
- Colonic surgery

Description
A White granular pöowder

DOSAGE AND ADMINISTRATION
FOR USE IN ADULTS ONLY
Oral administration.
The following is the recommended dose of reconstituted KLEARIT solution for adults.
Adults: Instruct patients to drink a total of up to 2 liters at a rate of 200 mL every 10 minutes, until 2 liters is consumed or the rectal effluent is clear. Rapid drinking of each portion is preferred to drinking small amounts continuously.
The first bowel movements should occur approximately one hour after the start of KLEARIT administration. Continue drinking until the watery stool is clear and free of solid matter.
The solution is more palatable if chilled prior to administration.
Patients may be allowed to consume water or clear liquids, in small quantities, after completion of the bowel preparation up until 2 hours before the time of the colonoscopy.

CONTRAINDICATIONS
KLEARIT is contraindicated in the following conditions:
- Hypersensitivity to the active substances or to any of the excipients
- Severe heart failure
- Serious deteriorations in general health such as dehydration
- Advanced carcinoma or any other colonic pathology causing excessive mucosal fragility
- Acute phases of intestinal tract inflammation including Crohn's disease and ulcerative colitis
- Gastrointestinal perforation or risk of perforation
- Toxic colitis or toxic megacolon
- Patients likely to have or who already have an ileus
- Patients likely to have or who already have a gastrointestinal obstruction or stenosis
- Gastric emptying disorders (e.g.: gastroparesis, gastric stasis)
- Children and teenagers under 18 years of age

SPECIAL PRECAUTION/ SPECIAL WARNINGS FOR USE
This product should be administered to elderly patients in frail general conditions only under medical supervision. Diarrhea provoked by the administration of KLEARIT is likely to result in considerable disturbance of the absorption of simultaneously administered drugs. This medicine contains polyethylene glycol (PEG) 3350. Allergic-type reactions have been reported with preparations based upon PEG: anaphylactic shock, rash, urticarial, angioedema.

Electrolyte disturbances are not expected with this product due to its isotonic composition; however, water-electrolyte disturbances have been exceptionally reported in at-risk patients. Patients with electrolyte abnormalities should have them corrected before administration of the bowel cleansing preparation. This product should be used with caution in patients with these conditions or in patients using concomitant medications that increase the risk of fluid and electrolytes disturbances including hyponatremia and hypokalemia, or may increase the risk of potential complications (such as patients with renal function altered, cardiac insufficiency or treated concomitantly with diuretics). In this case, patients should be appropriately monitored.

The product should be administered carefully and only under medical supervision in patients with a tendency to regurgitations or bedridden patients or patients with altered neurological function and /or motor disorders due to the risk of aspiration pneumonia. The product should be administered to these patients in a sitting position and eventually through an also-gastric probe. In patients with cardiac or renal in sufficiency, there is a risk of acute pulmonary oedema due to water overload.
This medicine contains sodium. This medicine contains 5.78 g of sodium per sachet. To be taken into account in patients with strict low-salt diet.

Ischaemic colitis
Post-marketing cases of ischaemic colitis, including serious, have been reported in patients treated with Polyethylene Glycol for bowel preparation. Polyethylene Glycol should be used with caution in patients with known risk factors for ischaemic colitis or in case of concomitant use of stimulant laxatives (such as bisacodyl or sodium picosulfate). Patients with sudden abdominal pain, rectal bleeding, or other symptoms of ischaemic colitis should be evaluated promptly.

DRUG INTERACTIONS AND OTHER INTERACTIONS
Prescriber should be informed of any other medicines taken simultaneously by the patient by oral route. Due to the stomach draining provoked by KLEARIT, the other oral treatments may not be absorbed and should be administered more than 2 hours before the draining solution. Avoid intake of oral treatments before and after laxative ingestion until the medical examination is completed. For medicines with a small therapeutic range or with a short half-life such as digoxin, anti-epileptics, coumarins, and immune suppressants, efficacy can be particularly affected.

ADVERSE EFFECTS
Diarrhea is an expected effect resulting from the use of Polyethylene Glycol 3350 with Electrolytes for oral solution. Nausea and vomiting have been reported at the start of administration, usually disappearing with continued administration.
The table below lists adverse reactions collected from clinical trial data, and adverse events reported from post-marketing sources. The frequencies are defined according to the following convention: Very common (>1/10), Common (>1/100 to<1/10), Uncommon (>1/1,000 to <1/100), Rare (>1/10,000 to<1/1,000), Very rare (<1/10,000), Unknown (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse reaction
Gastrointestinal disorders	Very common	Nausea Abdominal pain Abdominal distension
	Common	Vomiting
Immune system disorders	Unknown	Hypersensitivity (anaphylactic shock, angioedema, urticaria, rash, pruritus)

PREGNANCY AND LACTATION
Pregnancy
There or no or limited amount of data from the use of KLEARIT in pregnant women.
Studies in animals are insufficient to conclude on toxicity to reproductive functions. KLEARIT should only be used when necessary.
Nursing mothers
There is no or limited amount of data on the use of KLEARIT during breastfeeding. It is unknown whether Polyethylene Glycol 3350 is excreted in human milk. A risk to the newborns/infants cannot be excluded. Studies in animals are in sufficient to conclude on toxicity to reproductive functions. KLEARIT should only be used when necessary

OVERDOSE
Intentional or accidental ingestion of more than the recommended dose of KLEARIT powder for oral solution can result in severe diarrhea and electrolyte imbalance, including hyponatremia and hypokalaemia, as well as dehydration and hypovolaemia with the signs and related symptoms. In this case, the patient should be monitored, and copious amounts of fluids, especially fruit juices, should be given. In rare cases of overdose resulting in severe metabolic imbalance, intravenous rehydration may be performed.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Pharmacotherapeutic class: OSMOTIC LAXATIVE
ATC code A06AD65 (MACROGOL, COMBINATIONS)
Polyethylene Glycol 3350 is a long linear polymer on which water molecules are retained by hydrogen bonds. Following oral administration, they increase the volume of the intestinal fluids. The volume of non-absorbed intestinal fluid is responsible for the laxative properties of the solution.

PHARMACOKINETIC PROPERTIES
The electrolyte content of the powder is such that the reconstituted solution does not give rise to intestine/plasma electrolyte exchange. Pharmacokinetic findings confirm the absence of digestive absorption and bioconversion of Polyethylene Glycol 3350 after oral ingestion.

Preclinical safety data
Preclinical studies provide evidence that Polyethylene glycol 3350 has no significant systemic toxicity potential.

Instructions for Use
On the day prior to the colonoscopy, instruct patients to:
a) Take only clear liquids, but avoid red and purple liquids. Patients may consume a light breakfast. Early in the evening prior to the colonoscopy, obtain a food grade container with a volume of 2 liters. After cutting open the packet, pour the entire contents into the container. Add lukewarm water (to facilitate dissolution) to bring the volume of solution to 2 liters.
b) The solution is clear and colorless when reconstituted to a final volume of 2 liters.
c) After capping the container, shake vigorously several times to ensure that the ingredients are dissolved. When reconstituted use within 24 hours.

Shelf Life: 24 months

STORAGE CONDITIONS AND SHELF LIFE
Store below 30°C
When reconstituted, keep the solution refrigerated. Use within 24 hours, Discard unused portions.
Keep out of reach of children.
Further Information can be obtained from your doctor or pharmacist.
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Country of Origin: India
MAL No:

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