CIPEG Powder (Polyethylene glycol 3350)

Composition

CIPEG

Each dose (two spoonfuls) contains:

Polyethylene glycol 3350 ..... 17 g

Dosage Form

Powder for oral solution.

Pharmacology

Pharmacodynamics

Mechanism of Action

Polyethylene glycol (PEG) 3350 is an osmotic agent that causes retention of water in the stool resulting in a softer stool and more frequent bowel movements. It appears to have no effect on active absorption or secretion of glucose or electrolytes.

Effect on Gastric Motility

PEG 3350 increased fecal dry and wet weight, fecal water output and fecal volume without increasing the percent of fecal water and thereby stimulated gastrointestinal motility. This was considered an indirect effect of PEG 3350 and was not considered to be mediated via stimulation of the gastric enteric neuron.

Bowel Movement Frequency

In two separate studies, 151 and 23 patients with less than 3 bowel movements per week were randomized to PEG 3350, 17 grams, or placebo for 14 days. An increase in bowel movement frequency was observed for both treatment groups during the first week of treatment. PEG 3350 was statistically superior to placebo during the first and second week of treatment.

In a second study, 50 patients with 3 bowel movements or less per week and/or less than 300 grams of stool per week were randomized to 2 dose levels of PEG 3350 or placebo for 10 days each. Success was defined by an increase in both bowel movement frequency and daily stool weight. For both parameters, superiority of the 17 gram dose of PEG 3350 over placebo was demonstrated.

In a third study, 304 patients with 3 bowel movements or less per week were randomized to 17 grams of PEG 3350 or placebo for 6 months. Successful treatment according to the primary efficacy variable was seen in 52.0% of PEG 3350 and 11% of placebo subjects ($p < 0.001$). Similar efficacy was seen in a subgroup of 75 elderly subjects. According to the primary efficacy definition (based on individual treatment weeks), 61% of PEG 3350 treatment weeks versus 22% of the placebo weeks

were successful ($p < 0.001$). Similar results were observed when analyzed for differences due to gender, race or age. PEG 3350 laxative is safe and effective for use in patients with chronic constipation for 6 months.

Pharmacokinetics

Absorption

PEG 3350 passes unchanged along the gut. It is virtually unabsorbed from the gastro-intestinal tract. Any PEG 3350 that is absorbed is excreted via the urine.

Indications

For the treatment of constipation.

Dosage and Administration

The course of treatment with **CIPEG** should normally not exceed 2 weeks, although this can be repeated if required. As for all laxatives prolonged use is not usually recommended. Extended use may be necessary in the care of patients with severe chronic or resistant constipation, secondary to multiple sclerosis or Parkinson’s disease or induced by regular constipating medication in particular opioids and antimuscarinics.

Use two measuring spoonful of **CIPEG** (17 g) daily. Add this to a glass of water (120-240 ml), stir briskly and consume the contents immediately.

Contraindications

PEG 3350 is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients of the formulation; Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, ileus; severe inflammatory conditions of the intestinal tract, such as Crohn’s disease and ulcerative colitis; toxic megacolon.

Warnings and Precautions

General

If patients develop any symptoms indicating shifts of fluids/electrolytes like edema, shortness of breath, increasing fatigue, dehydration, cardiac failure, PEG 3350 should be stopped immediately. Electrolytes should be measured and any abnormality should be treated appropriately.

Patients with symptoms suggestive of bowel obstruction (nausea, vomiting, abdominal pain or distention) should be evaluated to rule out this condition before initiating PEG 3350 therapy. Patients presenting with complaints of constipation should have a thorough medical history and physical examination to detect associated metabolic, endocrine and neurogenic conditions, and medications. A diagnostic evaluation should include a structural examination of the colon.

Drug Interactions

PEG 3350 raises the solubility of medicinal products that are soluble in alcohol and relatively insoluble in water. PEG 3350 increases gastrointestinal transit rates which may transiently reduce

absorption of other medicinal products. There have been isolated reports of decreased efficacy with some concomitantly administered medicinal products, e.g. anti-epileptics

Renal impairment

No dosage change is necessary for patients with renal impairment.

Pregnancy Category C

Animal reproductive studies have not been performed with PEG 3350. It is also not known whether PEG 3350, can cause fetal harm when administered to a pregnant woman, or can affect reproductive capacity. PEG 3350 should only be administered to a pregnant woman if clearly needed.

Lactation

No effects on breast fed newborn/infant are anticipated since the systemic exposure of the breast feeding woman to PEG 3350 is negligible. PEG 3350 should be used with caution during breast feeding.

Geriatric Use

There is no evidence for special considerations when PEG 3350 is administered to elderly patients. It can be administered to elderly patients in the same dosage as recommended for adults.

Undesirable Effects

Gastrointestinal tract related reactions occur most commonly. These reactions may occur as a consequence of expansion of the contents of the gastrointestinal tract, and an increase in motility due to the pharmacological effects of PEG 3350. Mild diarrhea usually responds to dose reduction.

Other adverse events which may occur are:

Immune system disorders: Allergic reactions, including anaphylaxis, angioedema, dyspnea, rash, erythema, urticarial and pruritis

Metabolism and nutrition disorders: Electrolyte disturbances, particularly hyperkalemia and hypokalemia

Nervous system disorders: Headache

Gastrointestinal disorders: Abdominal pain, diarrhea, vomiting, nausea, dyspepsia, abdominal distention, borborygmi, flatulence, anal discomfort

General disorders and administration site conditions: Peripheral oedema

If you experience any side effects, talk to your doctor or pharmacist or write to **drugsafety@cipla.com**. You can also report side effects directly via the national pharmacovigilance program of India by calling on **1800 180 3024.**

By reporting side effects, you can help provide more information on the safety of this product.

Overdosage

Severe pain or distention, diarrhoea, vomiting may occur in case of overdosage. Severe pain or distension can be treated by nasogastric aspiration. Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

Shelf Life

2 years from the date of manufacture.

Storage and Handling Instructions

Store in a cool, dry place. Protect from light.

Packaging Information

CIPEG …… Box containing 121 g powder

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