PRESCRIBING INFORMATION: For the use of a Registerd Medical Practitioner only.

Polyethylene glycol, Sodium Chloride,
Sodium Hydrogen Carbonate & Potassium Chloride
Concentrate for Oral Solution

Looz PEG

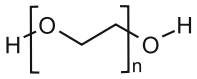
COMPOSITION

Each 25 ml contains:

Polyethylene glycol 3350 USP	13.125 g
Sodium Chloride IP	0.3507 g
Sodium Hydrogen Carbonate IP	0.1785 g
Potassium Chloride IP	0.0466 g

DESCRIPTION

Polyethylene Glycols or Macrogols are addition polymers of ethylene oxide and water, represented by the formula $H(OCH_2 CH_2)_n OH$ where n represents the average number of oxyethylene groups. Each macrogol is usually designated by a number that corresponds approximately to its average molecular weight. The chemical structure of PEG is given below



n represents average number of oxyethylene groups. Polyethylene Glycol (PEG) 3350, a white or almost white solid with a waxy or paraffin like appearance has an approximate average molecular weight of 3350 daltons. LOOZ PEG contains PEG 3350, Sodium Chloride, Sodium Hydrogen Carbonate and Potassium Chloride. When a 25 ml dose of LOOZ PEG is made up to 125 ml of solution, it provides 65 mmol/l of Sodium, 53 mmol/l of Chloride, 5.4 mmol/l of Potassium & 17 mmol/l of Hydrogen Carbonate which corresponds to 8.125 mmol of Sodium, 6.625 mmol of chloride, 0.675 mmol of Potassium and 2.125 mmol of Hydrogen Carbonate in each diluted dose of 125 ml.

DOSAGE FORM

Concentrate for Oral Solution, Clear, Colourless liquid.

INDICATION

For the treatment of chronic constipation.
For the treatment of faecal impaction, defined as refractory constipation with faecal loading of the rectum and / or colon.

DOSAGE & METHOD OF ADMINISTRATION

A course of treatment for constipation with LOOZ PEG should not normally 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.

Adults, adolescents and the elderly:

Constipation: 25 ml of solution diluted in 100 ml of water 1-3 times daily in divided doses, according to individual's response.
For extended use, the dose can be adjusted down to 1 or 2 doses per day of 25 ml of solution diluted in 100 ml of water.
Faecal impaction: 4 x 25 ml doses, each dose (25 ml) diluted in 100 ml of water, twice daily. A course of treatment does not normally exceed 3 days.

Patients with impaired cardiovascular function:

For the treatment of faecal impaction the dose should be divided so that no more than two doses are taken in any one hour.

Children:

Children aged 2 to 6 years: Usual starting daily dose is 12.5 ml solution diluted in 50 ml of water.
Children aged 7 to 11 years: Usual starting daily dose is 25 ml solution diluted in 100 ml of water.
The dose should be adjusted up or down as required to produce regular soft stools. If the dose needs increasing, it can be done every second day. The maximum dose of PEG 3350 does not normally exceed 26.252 g per day.

Administration

LOOZ PEG must not be taken undiluted and may only be diluted in water. Dilute required dose (volume) of LOOZ PEG with water as recommended under Dosage. Any unused solution should be discarded within 24 hours.

Dosage and Administration

This product must be diluted before use

For Adults, adolescents & elderly

Add 25 ml of LOOZ PEG Solution

Add 100 ml of drinking Water

Take 1-3 times daily in divided doses, according to individual response.

Extended use - 1 or 2 doses per day of 25 ml solution diluted in 100 ml water.

For Children

Age 2 to 6 years:
Usual starting daily dose is 12.5 ml solution diluted in 50 ml of water.

Age 7 to 11 years:
Usual starting daily dose is 25 ml solution diluted in 100 ml of water.

The maximum dose of PEG 3350 does not normally exceed 26.252 g per day.

USE IN SPECIAL POPULATION

Pregnancy: There is limited data on the use of PEG 3350 Concentrate for oral Solution in pregnant women. Studies in animals have shown indirect reproductive toxicity like reduction in fetal and placental weights, reduced fetal viability, increased limb and paw hyperflexion and abortions. Clinically, no effects during pregnancy are anticipated, since systemic exposure to PEG 3350 is negligible. PEG 3350 Concentrate for oral Solution can be used during pregnancy.

INTAS	AW No./AW Code :	LPN LZPEG PI 01		
	Size :	140 x 216 (mm)		
Pantone No. :	CMYK			
Date :	23/08/18, 10/09/18, 17/09/18			
Checked by :	Packaging Dev.	Packaging Dev.	C.Q.A.	Approved by C.Q.A.
Signature & Date				

Dimensions-
Open Size 140 x 216 mm (W x H)
Folded Size 140 x 27 mm (W x H)
No. of Folds, V0 x H3
GSM- 54 ± 10%
Paper Creamwove

Lactation: As systemic exposure of the breastfeeding woman to PEG 3350 is negligible, no effects on the breastfed new born/infant are anticipated, PEG 3350 Concentrate for oral Solution can be used during breast-feeding.

Pediatric Use: Can be administered to children aged 2 to 11 years for the treatment of chronic constipation as per the dosing as recommended under the section " Dosage & Method of Administration".

Geriatric Use: Can be administered to elderly patients in the same dosage as recommended for adults.

CONTRA INDICATIONS

Hypersensitivity to the active substances 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 & PRECAUTIONS

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

PEG 3350 Concentrate for Oral solution increases gastro-intestinal transit rate which may transiently reduce absorption of other medicinal products.
The sodium content should be taken into consideration when administering the product to patients on a controlled sodium diet.

No dosage change is necessary for the treatment of constipation in patients with renal insufficiency.

This contradicts dosage and indiction where fecal impaction is mentioned.

DRUG INTERACTIONS

Polyethylene Glycol raises the solubility of medicinal products that are soluble in alcohol and relatively insoluble in water.
PEG 3350 Concentrate for Oral solution increases gastro-intestinal transit rate 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.

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 pharmacologic effects of PEG 3350 Concentrate for Oral Solution. Mild diarrhoea usually responds to dose reduction.
Other adverse reactions which may occur are:
Immune system disorders: Allergic reactions, including anaphylaxis, angioedema, dyspnoea, rash, erythema, urticaria, and pruritis.
Metabolism and nutrition disorders: Electrolyte disturbances, particularly hyperkalaemia and hypokalaemia.
Nervous system disorders: Headache
Gastrointestinal disorders: Abdominal pain, diarrhoea, vomiting, nausea, dyspepsia, abdominal distension, borborygmi, flatulence, anal discomfort.
General disorders and administration site conditions: Peripheral oedema

OVER DOSAGE

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

PHARMACODYNAMIC & PHARAMACOKINETIC PROPERTIES

Pharmacodynamics

Pharmacotherapeutic group: Osmotically acting laxative.
Polyethylene Glycol 3350 acts by virtue of its osmotic action in the gut, which induces a laxative effect. PEG 3350 increases the stool volume, triggering the colon motility via neuromuscular pathways leading to an improved propulsive colonic transportation of the softened stools and a facilitation of the defecation.
Electrolytes combined with PEG 3350 are exchanged across the intestinal barrier (mucosa) with serum electrolytes and excreted in faecal water without net gain or loss of sodium, potassium and water.

Pharmacokinetics

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

INCOMPATIBILITIES

Not applicable.

PACKAGING INFORMATION

200 ml bottle packed in a mono carton.

STORAGE & HANDLING INSTRUCTIONS

Do not refrigerate or freeze. Discard product 30 days after first opening. The diluted solution should be kept covered. Throw away any solution not used within a 24 hour period.
Store at a temperature not exceeding 30°C.

Keep out of the reach of children.

Information compiled in February 2014.

Manufactured by: Lupin Ltd.
Zirakpur- Chandigarh Highway,
Swami Vivekanand School Road, Pabhat,
Zirakpur, Distt S.A.S Nagar
At: Plot no 23, EPIP-I, Jharmazri, Baddi-174103.
Dist. Solan (H.P.)

INTAS

Marketed by:
INTAS PHARMACEUTICALS LTD.
Matoda-382 210, Dist.: Ahmedabad. INDIA
LPN LZPEG PI 01

INTAS	AW No./AW Code :	LPN LZPEG PI 01		
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Pantone No. :	CMYK			
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