GOL™

Macrogol & Electrolytes

COMPOSITION

GOL™ Oral Solution: Each 25 ml concentrated oral solution contains Macrogol (3350) BP 13.125 gm, Sodium Bicarbonate BP 178.500 mg, Sodium Chloride BP 350.700 mg, Potassium Chloride BP 46.600 mg.

PHARMACOLOGY

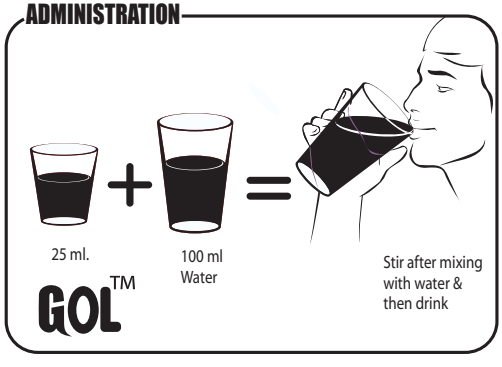
Macrogol (3350) exerts an osmotic action in the gut, which induces a laxative effect. Macrogol (3350) increases the stool volume, which triggers colon motility via neuromuscular pathways. The physiological consequence is an improved propulsive colonic transportation of the soften stools and a facilitation of the defecation. Electrolytes combined with Macrogol (3350) are exchanged across the intestinal barrier (mucosa) with serum electrolytes and excreted without net gain or loss of sodium, potassium and water. Macrogol (3350) is unchanged along the gut. It is virtually unabsorbed from the gastrointestinal tract.

INDICATION

For use in adults and children over 12 years of age for effective relief from constipation and treatment of chronic constipation. Also effective in resolving faecal impaction, defined as refractory constipation with faecal loading of the rectum and colon.

DOSAGE AND ADMINISTRATION

Measure 25 mL of **GOL**™ oral solution with measuring cup provided, then add this to 100 mL of water. Any unused diluted solution should be discarded within 24 hours.



Adults:

Constipation: 25 mL of **GOL**™ oral solution added to 100 mL of water once daily (to make a total volume of 125 mL). This may be increased to 2 – 3 doses of 25 mL daily (each 25 mL dose added to 100 mL of water), if required according to individual response.

Fecal Impaction: 8 doses of 25 mL daily (each 25 mL dose added to 100 mL of water). A course of treatment for faecal impaction does not normally exceed 3 days.

Children (12 -18 years): 25 mL of **GOL**™ oral solution added to 100 mL of water once daily.

CONTRAINDICATION

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 and toxic megacolon. Hypersensitivity to the active substances.

PRECAUTION

This medicinal product contains 8.125 mmol of sodium in each dose of 25 ml. The sodium content of **GOL**™ oral solution should be taken into consideration when administering the product to patients on a controlled sodium diet.

SIDE EFFECT

In the treatment of chronic constipation, diarrhoea or loose stools normally respond to a reduction in dose. Diarrhoea, abdominal distension, anorectal discomfort and mild vomiting are more often observed during the treatment for fecal impaction. Vomiting may be resolved if the dose is reduced or delayed.

USE IN PREGNANCY & LACTATION

Clinically, no effects during pregnancy are anticipated, since systemic exposure to Macrogol (3350) is negligible. **GOL**™ oral solution can be used during pregnancy.

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to Macrogol (3350) is negligible. **GOL**™ oral solution can be used during breast-feeding.

DRUG INTERACTION

There is a possibility that the absorption of other medicinal products could be transiently reduced during use with **GOL**™ oral solution. There have been isolated reports of decreased efficacy with some concomitantly administered medicinal products, e.g. anti-epileptics.

OVERDOSE

Extensive fluid loss by diarrhea or vomiting may require correction of electrolyte disturbances.

STORAGE

Store below 30°C and in a place protected from light. Do not refrigerate.

HOW SUPPLIED

GOL™ oral solution: Each box contains 100 ml concentrated oral solution in HDPE bottle with a measuring cup.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH