

New Zealand Datasheet

Name of Medicine

MOVICOL

Macrogol 3350

Presentation

MOVICOL is a free flowing white powder. Each sachet of MOVICOL contains:

Macrogol 3350	13.125 g
Sodium chloride	350.7 mg
Sodium bicarbonate	178.5 mg
Potassium chloride	46.6 mg

MOVICOL also contains a lime and lemon flavour and potassium acesulfame as a sweetener.

The content of electrolyte ions per sachet when made up to 125 mL is:

Sodium	65 mmol/L
Potassium	5.4 mmol/L
Chloride	53 mmol/L
Bicarbonate	17 mmol/L

Uses

Actions

ATC code: A06A D

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 softened stools and a facilitation of the defaecation. Electrolytes combined with macrogol 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.

The laxative action of macrogol has a time course, which will vary according to the severity of the constipation being treated. Faecal Impaction – In a non-comparative study in 27 adult patients, MOVICOL cleared the faecal impaction in 12/27 (44%) after 1 day's treatment, 23/27 (85%) after 2 day's treatment and 24/27 (89%) at the end of 3 days. Controlled comparative studies have not been performed with other treatments (eg. enemas).

Pharmacokinetics

Macrogol 3350 is unchanged along the gut. It is virtually unabsorbed from the gastrointestinal tract. Any macrogol 3350 that is absorbed is excreted via the urine.

Indications

For effective relief from constipation, treatment of chronic constipation. MOVICOL is also effective in resolving faecal impaction, defined as refractory constipation with faecal loading of the rectum and/or colon confirmed by physical examination of abdomen and rectum.

Dosage and Administration

Constipation: The dose is 1 sachet daily. This may be increased to 2-3 sachets daily, if required.

Faecal Impaction: 8 sachets daily, consumed within 6 hours. A course of treatment for faecal impaction 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 sachets are taken in any one hour.

Patients with renal insufficiency: No dosage change is necessary for treatment of either constipation or faecal impaction.

Administration

For oral administration. Each sachet should be dissolved in 125 mL water. For faecal impaction 8 sachets may be dissolved in 1 litre of water. Store the solution refrigerated and discard any solution not used within 6 hours.

Contraindications

Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, ileus and severe inflammatory conditions of the intestinal tract, such as Crohn's disease, ulcerative colitis and toxic megacolon.

Known hypersensitivity to macrogol or any of the excipients.

Warnings and Precautions

Mild adverse reactions are possible as described under Adverse Effects. If patients develop any symptoms indicating shifts of fluid/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure) MOVICOL should be stopped immediately and electrolytes measured, and any abnormality should be treated appropriately.

Prolonged use is undesirable and may lead to dependence. Patients should be advised to drink plenty of water and increase fibre in the diet.

Mutagenicity and Carcinogenicity

Preclinical studies show that macrogol 3350 has no significant systemic toxicity potential, although no tests of its genotoxicity have been conducted.

Use in Children

Macrogol 3350 paediatric dosage (MOVICOL-Half) is recommended for use in children aged 2 years and above

Use in Pregnancy and Lactation

There is no experience of the use of MOVICOL during pregnancy and lactation. No preclinical tests of its effects on reproduction have been conducted.

MOVICOL should only be used if considered essential by the physician.

Effects on Ability to Drive and Use Machines

None known.

Adverse Effects

Abdominal distention and pain, borborygmi and nausea, attributable to the expansion of the contents of the intestinal tract, can occur. Mild diarrhoea, which usually responds to dose reduction. Allergic reactions including anaphylaxis are a possibility.

Interactions

No clinical interactions have been reported. Macrogol raises the solubility of drugs that are soluble in alcohol and relatively insoluble in water. There is, therefore, a theoretical possibility that the absorption of such drugs could be transiently reduced. A theoretical potential also exists for decreased absorption (rate and extent) of drugs which are generally poorly absorbed or are contained in sustained or modified release dosage forms. This is more likely to occur if MOVICOL is overdosed to induce watery diarrhoea.

Overdosage

Severe pain or distention can be treated by nasogastric aspiration. Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

Pharmaceutical Precautions

Store below 25°C.

Store the solution refrigerated and discard any solution not used within 6 hours.

Each sachet should be dissolved in 125 mL water. For faecal impaction 8 sachets may be dissolved in 1 litre of water.

Medicine Classification

General Sale Medicine.

Package Quantities

Boxes of 8, 20 or 30 sachets each containing 13.125 g of macrogol 3350.

Further Information

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