

MOVICOL[®] Abbreviated Prescribing Information

REFER TO FULL SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
BEFORE PRESCRIBING

Presentation:

Sachet of white powder which dissolves in about 125ml (approximately ½ glassful) water to make a lemon/lime flavoured drink. Each sachet contains: 13.125g macrogol (polyethylene glycol) 3350, 178.5mg sodium bicarbonate, 350.7mg sodium chloride and 46.6mg potassium chloride.

Uses:

Treatment of chronic constipation and faecal impaction.

Dosage and administration:

Chronic Constipation: Adults, adolescents and the elderly: 1-3 sachets daily in divided doses, according to individual response.

For extended use: adjust dose down to 1 or 2 sachets.

Children (below 12 years): not recommended. See MOVICOL Paediatric Plain.

Extended use may be necessary in patients with severe chronic or resistant constipation, secondary to multiple sclerosis or Parkinson's Disease, or induced by regular constipating medicine, in particular opioids and antimuscarinics.

A course of MOVICOL treatment does not normally exceed 2 weeks, but can be repeated if required.

Faecal Impaction: Adults, adolescents and the elderly: 8 sachets per day. A course of treatment for faecal impaction does not normally exceed 3 days. The 8 sachets should be taken over 6 hours (2 sachets per hour maximum in cardiovascular impairment).

The 8 sachets may be dissolved in 1 litre of water.

Children (below 12 years): not recommended. See MOVICOL Paediatric Plain.

Contra-indications, warnings etc:

Contra-indications: Intestinal perforation or obstruction due to structural or functional disorders of the gut wall, ileus and severe inflammatory conditions of the intestinal tract, such as Crohn's disease, ulcerative colitis and toxic megacolon. Hypersensitivity to polyethylene glycol (macrogol), or any of the excipients.

Warnings: Symptoms indicating fluid/electrolyte shift.

Interactions:

Medicinal products taken within 1 hour of administration of large volumes of macrogol preparations (as used when treating faecal impaction) may be flushed from the gastrointestinal tract and not absorbed. No interactions with other medicinal products reported.

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Pregnancy and lactation:

No data on use in pregnancy and lactation and should only be used if considered essential by a physician.

Side effects: *Common:* Abdominal distension and pain, borborygmi, nausea and diarrhoea are common side effects in high dose use when treating faecal impaction and are less common in lower dose use for treating constipation.

Very rare: Allergic reactions.

Refer to the Summary of Product Characteristics (SmPC) for full list and frequency of adverse events.

Overdose:

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

Pharmaceutical Particulars:

Do not store sachet above 25°C. Reconstituted solution should be stored covered in a refrigerator (2-8 °C) for up to 6 hours.

LEGAL CATEGORY: P

COST: 20 sachets: £4.45. 30 sachets: £6.68. 50 sachets: £ 11.13.

MARKETING AUTHORISATION NUMBER: PL 00322/0070

For further information contact:



Norgine Pharmaceuticals Limited
Moorhall Road
Harefield
Middlesex
UB9 6NS
01895 826606
E-mail: medinfo@norgine.com

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Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Medical Information at Norgine Pharmaceuticals Ltd on 01895 826606.