

**UK PRESCRIBING INFORMATION: Moviprep and Moviprep Orange
(Macrogol 3350, sodium sulfate anhydrous, ascorbic acid, sodium ascorbate,
sodium chloride and potassium chloride)**

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

Presentation: Powder for oral solution contained in two separate sachets, A and B. Sachet A contains macrogol 3350 100g; sodium sulfate anhydrous 7.5g; sodium chloride 2.691g and potassium chloride 1.015g. Sachet B contains ascorbic acid 4.7g and sodium ascorbate 5.9g.

Uses: Bowel cleansing prior to any clinical procedure requiring a clean bowel.

Dosage and administration: For oral use. **Adults and Older People:** A course of treatment consists of two litres of Moviprep / Moviprep Orange. A litre consists of one sachet A and one sachet B dissolved together in water to make one litre of solution. The reconstituted solution should be drunk over a period of one to two hours. This process should be repeated with a second litre to complete the course. A further litre of clear fluid is recommended during the course of treatment.

This course of treatment can be taken either as divided or as single doses and timing is dependent on whether the clinical procedure is conducted with or without general anaesthesia as specified below:

For procedures conducted under general anaesthesia:

1. Divided doses: one litre in the evening before and one litre in the early morning of the day of the clinical procedure. Ensure consumption of Moviprep / Moviprep Orange as well as any other clear fluids has finished at least two hours before the start of the clinical procedure.
2. Single dose: two litres in the evening before the clinical procedure or two litres in the morning of the clinical procedure. Ensure consumption of Moviprep / Moviprep Orange as well as any other clear fluids has finished at least two hours before the start of the clinical procedure.

For procedures conducted without general anaesthesia:

1. Divided doses: one litre in the evening before and one litre in the early morning of the day of the clinical procedure. Ensure consumption of Moviprep / Moviprep Orange as well as any other clear fluids has finished at least one hour before the start of the clinical procedure.
2. Single dose: two litres in the evening before the clinical procedure or two litres in the morning of the clinical procedure. Ensure consumption of Moviprep / Moviprep Orange has finished at least two hours before the start of the clinical procedure. Ensure consumption of any clear fluids has finished at least one hour before the clinical procedure.

Patients should be advised to allow for appropriate time to travel to the colonoscopy unit.

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No solid food should be taken from the start of the course of treatment until after the clinical procedure.

Children: Not recommended below 18 years of age.

Contraindications:

Known or suspected hypersensitivity to any of the ingredients, gastrointestinal obstruction or perforation, disorders of gastric emptying, ileus, phenylketonuria, glucose-6-phosphate dehydrogenase deficiency, toxic megacolon which complicates very severe inflammatory conditions of the intestinal tract including Crohn's disease and ulcerative colitis. Do not use in unconscious patients.

Warnings and precautions: Diarrhoea is an expected effect. Administer with caution to fragile patients in poor health or patients with serious clinical impairment such as impaired gag reflex, or with a tendency to aspiration or regurgitation, impaired consciousness, severe renal insufficiency (creatinine clearance <30 mL/min), cardiac impairment (NYHA grade III or IV), those at risk of arrhythmia (e.g. those on treatment for cardiovascular disease or who have thyroid disease), dehydration, severe acute inflammatory bowel disease.

Dehydration, if present, should be corrected before using Moviprep / Moviprep Orange. The reconstituted Moviprep / Moviprep Orange does not replace regular fluid intake and adequate fluid intake must be maintained.

Semi-conscious patients or patients prone to aspiration or regurgitation should be closely monitored during administration, particularly if this is via a nasogastric route. If symptoms indicating arrhythmia or shifts of fluid or electrolytes occur, plasma electrolytes should be measured, ECG monitored and any abnormality treated appropriately. In debilitated fragile patients, patients with poor health, those with clinically significant renal impairment, arrhythmia and those at risk of electrolyte imbalance, the physician should consider performing a baseline and post-treatment electrolyte, renal function test and ECG as appropriate. The possibility of serious arrhythmias, predominantly in those with underlying cardiac risk factors and electrolyte disturbance cannot be ruled out. If patients experience symptoms which make it difficult to continue the preparation, they may slow down or temporarily stop consuming the solution and should consult their doctor. Moviprep Orange is not recommended for patients with glucose-galactose malabsorption.

Post-marketing cases of ischaemic colitis, including serious, have been reported in patients treated with macrogol for bowel preparation. Macrogol should be used with caution in patients with known risk factors for ischaemic colitis or in case of concomitant use of stimulant laxatives (such as bisacodyl or sodium picosulfate). Patients presenting with sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis should be evaluated promptly.

Moviprep/Moviprep Orange contains 363.2 mmol (8.4g) of sodium per course of

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treatment (two litres) equivalent to 420% of the WHO recommended maximum daily intake of 2g of sodium for an adult. To be taken into consideration by patients on a controlled sodium diet. Only a proportion (up to 112.4 mmol (2.6g) per course of treatment) of sodium is absorbed. It also contains 28.4 mmol (1.1g) of potassium per two litres. To be taken into consideration in patients with reduced kidney function or patients on a controlled potassium diet.

Interactions: Oral medication should not be taken within one hour of administration as it may be flushed from the GI tract and not absorbed.

Fertility, pregnancy and lactation: There are no data on the effects on fertility. There are no data on the use in pregnancy or lactation so it should only be used if judged essential by the physician.

Effects on ability to drive and use machines: No influence on the ability to drive and use machines

Side Effects: **Very common:** abdominal pain, nausea, abdominal distension, anal discomfort, malaise and pyrexia. **Common:** sleep disorder, dizziness, headache, vomiting, dyspepsia, rigors, thirst and hunger. **Uncommon:** dysphagia, abnormal liver function tests and discomfort. **Not known:** allergic reaction including anaphylactic reaction, dyspnoea and allergic skin reactions including angioedema, urticaria, pruritus, rash, erythema; electrolyte disturbances including blood bicarbonate decreased, hyper and hypocalcaemia, hypophosphataemia, hypokalaemia and hyponatremia and changes in the blood chloride levels; dehydration; convulsions associated with severe hyponatraemia; transient increase in blood pressure; arrhythmia, palpitations; flatulence and retching.

Refer to the SmPC for a full list and frequency of adverse events.

UNITED KINGDOM:

Price and pack sizes: Lemon- or orange-flavoured powder in sachets, 1 treatment pack (2 x sachet A + 2 x sachet B) £10.36.

Legal category: Pharmacy medicine.

MA Number: PL 20011/0039 (Moviprep); PL 20011/0006 (Moviprep Orange).

MA Holder: Norgine Pharmaceuticals Limited, Norgine House, Widewater Place, Moorhall Road, Harefield, Uxbridge, UB9 6NS, UK.

Additional information is available on request or in the SmPC. For further information contact: Norgine Pharmaceuticals Limited, Norgine House, Moorhall Road, Harefield, Uxbridge, UB9 6NS, UK. Tel: +44(0)1895 826606. Email: medinfo@norgine.com

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United Kingdom

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Norgine Pharmaceuticals Ltd on: Tel: +44 (0)1895 826 606. Email: medinfo@norgine.com