MOVIPREP® Prescribing Information

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

Presentation: A box containing two transparent bags, each containing two separate sachets, A and B. Sachet A contains macrogol 3350 100g; sodium sulphate anhydrous 7.5g; sodium chloride 2.691g and potassium chloride 1.015g as white to yellow powder. Sachet B contains ascorbic acid 4.7g and sodium ascorbate 5.9g as white to light brown powder. MOVIPREP also contains aspartame (E951), acesulfame potassium (E950) and lemon flavour.

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

Dosage and administration: *Adults and elderly***:** A course of treatment consists of two litres of MOVIPREP. A further litre of clear fluid is recommended during the course of treatment. A litre of MOVIPREP® consists of one Sachet A and one Sachet B dissolved in water. This reconstituted solution should be drunk over a period of one to two hours. This should be repeated with a second litre of MOVIPREP. The two litres of MOVIPREP may be consumed either as a divided dose, 1L the evening before the procedure and 1L in the early morning of the procedure, or as a single dose the evening before the procedure. There should be at least one hour between the end of intake and the start of the procedure. No solid food should be taken from the start of the treatment and until after the procedure. *Children:* Not recommended in children below 18 years of age.

Contra-indications, warnings etc: *Contra-indications:* Known or suspected gastrointestinal obstruction or perforation; disorders of gastric emptying; ileus; phenylketonuria; glucose-6-phosphodehydrogenase deficiency; toxic megacolon complicating severe inflammatory conditions of the GI tract or hypersensitivity to any of the ingredients. Do not use in unconscious patients. *Warnings:* Diarrhoea is an expected effect. Administer with caution in fragile patients in poor health or serious clinical impairment such as severe renal insufficiency, cardiac impairment (NYHA grade III or IV), severe acute inflammatory disease or severe dehydration and those with an impaired gag reflex or impaired consciousness. Dehydration, if present, should be corrected before using MOVIPREP. Patients prone to aspiration should be closely monitored during administration, particularly if this is via a naso-gastric tube. If symptoms indicating shifts of fluid or electrolytes occur, plasma electrolytes should be measured and any abnormality treated appropriately. In debilitated fragile patients, patients with poor health, those with clinically significant renal impairment and those at risk of electrolyte imbalance, the physician should consider performing baseline and post-treatment electrolyte and renal function test. 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.

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

Pregnancy and lactation: There is no experience of use in pregnancy or lactation so it should only be used if judged essential by the physician.

Side Effects: *Very common:* abdominal pain, nausea, abdominal distension, anal discomfort, malaise, thirst. *Common:* Vomiting, dyspepsia, hunger, sleep disorder, dizziness, and rigors. *Uncommon:* Hypophosphataemia, headache, dysphagia, discomfort. Allergic reactions including rash, urticaria, oedema and anaphylaxis are a possibility. Refer to the Summary of Product Characteristics (SmPC) for full list and frequency of adverse events.

Overdose: In case of gross accidental overdosage, conservative measures are usually sufficient. In the rare event of severe metabolic derangement, intravenous rehydration may be used.

Pharmaceutical Particulars: *Sachets:* Store in the original package below 25^{o}C. *Reconstituted solution:* Keep covered; May be stored for up to 24 hours below 25^{o}C or in a refrigerator.

Legal Category: P
Packs: One pack of MOVIPREP contains a single treatment.
Basic NHS Price: UK £ 9.87 IRE €13.26
Marketing Authorisation Number: PL 20142/0005 PA 1336/01/01

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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