Product Information

MOVIPREP®
Powder for Solution

NAME OF THE MEDICINE:
MOVIPREP

DESCRIPTION:
The ingredients of MOVIPREP are contained in two separate sachets:

Sachet A:

Macrogol 3350	100 g
Sodium sulfate anhydrous	7.5 g
Sodium chloride	2.691 g
Potassium chloride	1.015 g

Sachet B:

Ascorbic acid	4.7 g
Sodium ascorbate	5.9 g

The concentration of electrolyte ions when both sachets are made up to 1 litre of solution is:

Sodium	181.6 mmol/L (of which no more than 56.2 mmol is absorbable)
Sulfate	52.8 mmol/L
Chloride	59.8 mmol/L
Potassium	14.2 mmol/L
Ascorbate	29.8 mmol/L

The product contains excipient ingredients: aspartame, acesulfame potassium, and lemon flavour (contains maltodextrin, citral, lemon oil, lime oil, xanthan gum, vitamin E).

PHARMACOLOGY:
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.

Ascorbic acid is absorbed mainly at the small intestine level by a mechanism of active transport, which is sodium dependent and saturable. There is an inverse relationship between the ingested dose and the percentage of the dose absorbed. For oral doses between 30 and 180 mg an amount of 70-85% of the dose is absorbed. Following oral intake of up to 12 g ascorbic acid, it is known that only 2 g is absorbed. After high oral doses of ascorbic acid and when plasma concentrations exceed about 15 mg/L, the absorbed ascorbic acid is mainly eliminated unchanged in the urine.

The pharmacokinetics of MOVIPREP have not been studied in patients with renal or hepatic insufficiency.

Macrogol 3350, sodium sulfate and high doses of ascorbic acid exert 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 a propulsive colonic transportation of the softened stools. The electrolytes present in the formulation and the supplementary clear liquid intake are included to prevent clinically significant variations in sodium, potassium or water, and therefore reduce dehydration risk.

INDICATIONS:
For bowel cleansing prior to any clinical procedure requiring a clean bowel, e.g., bowel endoscopy, lower gastrointestinal tract radiology or digestive tract surgery.

CONTRAINDICATIONS:
Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, ileus, gastric retention, and severe inflammatory conditions of the intestinal tract, such as Crohn's disease, ulcerative colitis and toxic megacolon. Phenylketonuria (due to the presence of aspartame), glucose-6-phosphodehydrogenase deficiency (patients may be at risk of acute haemolysis due to the presence of ascorbate), known hypersensitivity to any of the ingredients. Do not use in unconscious patients, or patients with severe dehydration.

PRECAUTIONS:
The fluid content of MOVIPREP when re-constituted with water does not replace regular fluid intake and adequate fluid intake must be maintained.

Diarrhoea is an expected effect resulting from the use of MOVIPREP.

MOVIPREP should be administered with caution to frail patients in poor health, or patients with impaired gag reflex or serious clinical impairment such as:

- Moderate or severe renal insufficiency (creatinine clearance <30 mL/min)
- cardiac failure (NYHA Grade III or IV)
- those at risk of arrhythmia, for example those on treatment for cardiovascular disease or who have thyroid disease*
- dehydration
- severe acute inflammatory bowel disease
- pre-existing serum electrolyte disturbance

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.

There have been rare reports of serious arrhythmias including atrial fibrillation associated with the use of ionic osmotic laxatives for bowel preparations. These occur predominantly in patients with underlying cardiac risk factors and electrolyte disturbance.

Patients with insulin-dependent diabetes should consult their physician prior to use of MOVIPREP. Only liquids should be consumed during usage of MOVIPREP, therefore insulin dosing should be balanced accordingly.
The presence of dehydration should be corrected before the use of MOVIPREP.

Semi-conscious patients or patients prone to aspiration or regurgitation should be closely monitored during administration, especially if administered via nasogastric tube.

If patients develop any symptoms indicating arrhythmia or shifts of fluid/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, or cardiac failure) plasma electrolytes should be measured, ECG monitored and any abnormality treated appropriately.

If a patient experiences severe bloating, abdominal distension, or abdominal pain, administration should be slowed or temporarily discontinued until the symptoms abate.

Contraceptive cover from the oral contraceptive pill is likely to be incomplete if it is taken at any time during the process of bowel cleansing with MOVIPREP (an hour before the first dose of MOVIPREP until after the investigation). Therefore an alternative method of contraception should be used for the length of the cycle when MOVIPREP is taken.

Use in pregnancy: There is no experience of the use of MOVIPREP during pregnancy. MOVIPREP should only be used if considered essential by the physician.

Use in lactation: There is no experience of the use of MOVIPREP during lactation. MOVIPREP should only be used if considered essential by the physician.

Paediatric Use: The safety and efficacy of MOVIPREP has not been studied in the paediatric population therefore it is not recommended for use in children below 18 years.

Preclinical safety data:
Preclinical studies show that macrogol 3350, ascorbic acid, and sodium sulfate have no significant systemic toxicity potential.

INTERACTIONS WITH OTHER MEDICINES:
Oral medication should not be taken within one hour of administration of MOVIPREP, as it may be flushed from the gastrointestinal tract and not absorbed.

Specific consideration should be given to sustained release formulations and products with a narrow therapeutic window. Please refer to “Precautions” for advice on oral contraceptives.

ADVERSE EFFECTS:*
Diarrhoea is an expected outcome of bowel preparation.

Due to the nature of the intervention, undesirable effects occur in the majority of patients during the process of bowel preparation. Whilst these vary between preparations, nausea, vomiting, bloating, abdominal pain, anal irritation and sleep disturbance commonly occur in patients undergoing bowel preparation. Dehydration may occur as a result of diarrhoea and/or vomiting.
As with other bowel cleansing products containing macrogol, allergic reactions including rash, urticaria, pruritus, dyspnoea, angioedema and anaphylaxis have been reported

Data from clinical studies are available in a population of 825 patients treated with MOVIPREP in which undesirable effect data were actively elicited. Additionally, adverse events reported in post-marketing are included.
The frequency of adverse reactions to MOVIPREP is defined using the following convention:

Very common	≥ 1/10 (≥ 10%)
Common	≥ 1/100, < 1/10 (≥ 1%, < 10%)
Uncommon	≥ 1/1,000, < 1/100 (≥ 0.1%, < 1%)
Rare	≥ 1/10,000, < 1/1,000 (≥ 0.01%, < 0.1%)
Very rare	< 1/10,000 (< 0.01%)
Not known (cannot be estimated from the available data)	

Body System	**Frequency**	**Adverse Drug Reaction**
Immune system disorders	Not known	Allergic reaction including anaphylactic reaction, dyspnoea and skin reactions (see below)"
Metabolism and Nutrition Disorders	Not known	Electrolyte disturbances including blood bicarbonate decreased, hyper and hypo calcaemia, hypophosphataemia, hypokalaemia and hyponatraemia, and changes in the blood chloride level. Dehydration.
Psychiatric disorders	Common	Sleep disorder.
Nervous system disorders	Common	Dizziness, headache.
	Not known	Convulsions associated with severe hyponatraemia.
Cardiac disorders	Not known	Transient increase in blood pressure. Arrhythmia, palpitations
Gastrointestinal disorders	Very common	Abdominal pain, nausea, abdominal distension, anal discomfort.
	Common	Vomiting, dyspepsia.
	Uncommon	Dysphagia.
	Not known	Flatulence, retching.
Hepatobiliary disorders	Uncommon	Abnormal liver function tests.
Skin and subcutaneous tissue disorders	Not known	Allergic skin reactions including angioedema, urticaria, pruritis, rash, erythema
General disorders and administration site conditions	Very common	Malaise, pyrexia
	Common	Rigors, thirst, hunger.
	Uncommon	Discomfort.

DOSAGE AND ADMINISTRATION:

A course of treatment consists of two litres of MOVIPREP.

It is strongly recommended that patients also drink a further one litre of clear liquid to prevent them from feeling thirsty and becoming dehydrated. “Clear liquids” include:

- water,
- clear soup,
- tea or coffee without milk or non-dairy creamer,
- all of the following liquids which are not coloured red or purple: fruit juices without pulp, carbonated and non-carbonated soft drinks, fruit flavoured cordials.

Note: patients should not drink anything coloured red or purple.

A litre of MOVIPREP consists of one “Sachet A” and one “Sachet B” dissolved together in water to make a one litre solution. The reconstituted solution should be drunk over a period of one to two hours. This process should be repeated with a second litre of MOVIPREP to complete this course.

This course of treatment can be taken either as divided (split) or single doses as specified below:

1. Divided doses: one litre of MOVIPREP in the evening before and one litre of MOVIPREP in the early morning of the day of the procedure

2. Single dose: two litres in the evening preceding the clinical procedure or two litres in the morning of the clinical procedure

For both the divided dose and the 2 litre dose taken the evening before the procedure, there should be at least one hour between the end of intake of fluid (MOVIPREP or clear liquid) and the start of the colonoscopy.

For the 2 litre dose taken in the morning of the procedure, there should be at least two hours between the end of intake of MOVIPREP and at least one hour between the end of intake of any clear liquid and the start of the colonoscopy.

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

For patients taking the divided dose or the 2 litre dose taken the evening before the procedure, no solid food or liquids (other than the clear fluids listed above) should be taken from the start of the course of MOVIPREP treatment until after the clinical procedure.

For patients taking the 2 litre dose in the morning of the procedure, no solid food or liquids (other than the clear fluids listed above) should be taken from 6 pm the night before the procedure until after the clinical procedure.

Reconstitution of MOVIPREP in water may take up to 5 minutes and is best performed by adding the powder to the mixing vessel first followed by the water. The patient should wait until all the powder has dissolved before drinking the solution.

After reconstitution, the MOVIPREP solution may be used immediately or if preferred may be cooled before use. The reconstituted solution should be used within 24 hours.

OVERDOSAGE:
In case of gross accidental overdosage, where diarrhoea is severe, conservative measures are usually sufficient, generous amounts of fluid should be given. Further information on the latest overdosage treatment can be obtained by contacting the following Poisons Information Centres: 13 11 26 (Australia) or 0800 764 766 (New Zealand).

PRESENTATION AND STORAGE CONDITIONS:
One pack of MOVIPREP contains a single treatment of two bags. Each bag contains one Sachet A containing 112 g of powder, and one Sachet B containing 11 g of powder**.** AUST R 155398.

Sachets : Store below 25°C. Shelf life 3 years
Reconstituted solution: Store below 25°C, or store in refrigerator. Keep solution covered. Shelf life of solution 24 hours.

NAME AND ADDRESS OF THE SPONSOR:
Norgine Pty Limited. 3/14 Rodborough Road, Frenchs Forest, NSW 2086.

POISON SCHEDULE OF THE MEDICINE:
Schedule 3. Pharmacist Only Medicine:

DATE OF FIRST INCLUSION IN THE ARTG:
25 September 2008

DATE OF MOST RECENT AMENDMENT:
26 June 2015

NORGINE

***Please note changes in Product Information**