

# New Zealand Datasheet

## Name of Medicine

MOVIPREP

## Presentation

MOVIPREP is an oral powder for solution consisting of a free flowing white to yellow powder in Sachet A and a free flowing white to light brown powder in Sachet B.

Sachet A contains the following active ingredients:

Macrogol 3350	100 g
Sodium sulphate anhydrous	7.500 g
Sodium chloride	2.691 g
Potassium chloride	1.015 g

Sachet B contains the following active ingredients:

Ascorbic acid	4.700 g
Sodium ascorbate	5.900 g

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

Sodium	181.6 mmol/l (of which not more than 56.2 mmol is absorbable)
Sulphate	52.8 mmol/l
Chloride	59.8 mmol/l
Potassium	14.2 mmol/l
Ascorbate	29.8 mmol/l

For excipients, see Further Information

## Uses

### Actions

Pharmacotherapeutic group: A06A D

Macrogol 3350, sodium sulphate and high doses of ascorbic acid exert an osmotic action in the gut, which induce a laxative effect. The electrolytes present in the formulation as well as the supplementary clear liquid intake ensure that there are no clinically significant variations of sodium, potassium or water, and thus no dehydration risk.

### Pharmacokinetics

Macrogol 3350 is unchanged along the gut. It is virtually unabsorbed from the gastro-intestinal 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 14

mg/litre, the absorbed ascorbic acid is mainly eliminated unchanged in the urine.

Macrogol 3350, sodium sulfate and high dose 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.

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

## **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.

## **Dosage and Administration**

### **Adults and elderly:**

A course of treatment consists of two litres of MOVIPREP. Drink a further one litre of clear liquid to prevent you from feeling very 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 one litre of 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.

This course of treatment can be taken:

- either divided as one litre of MOVIPREP in the evening before and one litre of MOVIPREP in the early morning of the day of the clinical procedure.
- or, in the evening preceding the clinical procedure.
- or, early in the morning of the day of the clinical procedure

There should be at least one hour between the end of intake of fluid (MOVIPREP or clear liquid) and the start of colonoscopy.

No solid food should be taken from the start of the course of treatment 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.

**Children:**

Not recommended in children below 18 years of age, as MOVIPREP has not been studied in the paediatric population.

**Contraindications**

Do not use in patients with known or suspected:

- 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 (due to presence of ascorbate)
- known hypersensitivity to any of the ingredients

Do not use in unconscious patients or patients with severe dehydration.

**Warnings and Precautions**

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 to severe renal insufficiency (creatinine clearance <30 ml/min)
- cardiac failure (NYHA Grade III or IV)
- dehydration
- severe acute inflammatory bowel disease
- pre-existing serum electrolyte disturbance

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

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 a naso-gastric tube.

If patients develop any symptoms indicating shifts of fluid/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, cardiac failure), plasma electrolytes should be measured 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.

Patients with insulin-dependant 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.

**Use in Pregnancy and Lactation**

There is no experience of the use of MOVIPREP during pregnancy and lactation.

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

### Use in Children

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.

### Effects on Ability to Drive and Use Machines

There is no known effect on the ability to drive and use machines.

### 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.

As with other bowel cleansing products containing macrogol, allergic reactions including rash, urticaria, pruritus, 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 postmarketing 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	Anaphylaxis.
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.
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	Pruritus, urticaria, rash.
General disorders and administration site conditions	Very common	Malaise.
	Common	Rigors, thirst, hunger.
	Uncommon	Discomfort.
Investigations	Not known	Electrolytes disturbances including blood bicarbonate decreased, hypercalcaemia, hypocalcaemia, hypophosphataemia, hyponatraemia (occurs more commonly in patients taking concomitant medication affecting the kidneys such as ACE inhibitors and diuretics) and changes in the blood chloride levels.

## Interactions

Oral medication should not be taken within one hour of administration of MOVIPREP as it may be flushed from the gastro-intestinal tract and not absorbed.

Specific consideration should be given to sustained release formulations and products with a narrow therapeutic window.

Please refer to “Warnings and Precautions” for advice on oral contraceptives.

## Overdosage

In case of gross accidental overdosage, where diarrhoea is severe, conservative measures are usually sufficient; generous amounts of fluid, especially fruit juices, should be given.

Further information on the latest overdose treatment can be obtained by contacting the following Poison’s Information Centres:

In Australia, please call 13 11 26

In New Zealand, please call 0800 POISON or 0800 764766

## Pharmaceutical Precautions

Sachets: Do not store above 25°C. Store in the original package.

Reconstituted Solution: Do not store above 25°C. Alternatively, store at 2-8°C (in a refrigerator). Keep solution covered. Discard unused reconstituted solution after 24 hours.

## **Medicine Classification**

Pharmacist-Only Medicine.

## **Package Quantities**

MOVIPREP consists of a paper/LDPE/aluminium/LDPE sachet containing 112 g of powder (sachet A) and a paper/LDPE/aluminium/LDPE sachet containing 11 g of powder (sachet B). Both sachets are contained in a transparent bag. One pack of MOVIPREP contains a single treatment of two bags.

## **Further Information**

### **Excipients**

Aspartame (E951), Acesulfame Potassium (E 950), Lemon flavour containing maltodextrin, citral, lemon oil, lime oil, xanthan gum, vitamin E.

### **Incompatibilities**

None are known.

## **Name and Address**

Sponsor:

CARSL Consulting

PO Box 480

Pukekohe

Ph (09) 238 3447

Fax (09) 238 9239

for Norgine Pty Limited

Distributor:

Pharmacy Retailing (NZ) Ltd

Trading as Healthcare Logistics

58 Richard Pearse Drive

Airport Oaks

PO Box 62-027

Mt Wellington

Auckland

Telephone: (09) 918 5100

Fax: (09) 918 5101

## **Date of Preparation**

1 December 2010