New Zealand Datasheet

1 PRODUCT NAME
MOVIPREP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Sachet A contains the following active ingredients:

Macrogol 3350	100 g
Sodium sulfate 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)
Sulfate	52.8 mmol/l
Chloride	59.8 mmol/l
Potassium	14.2 mmol/l
Ascorbate	56.5 mmol/l

Contains aspartame.

The complete treatment contains 8.4 g of sodium and 1.2 g of potassium.

For excipients, see section 6.1

3 PHARMACEUTICAL FORM
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.

4 CLINICAL PARTICULARS
4.1 Therapeutic 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.

4.2 Dose and method of administration
Adults and elderly:
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 the course.

This course of treatment can be taken either as divided (split) or 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 of MOVIPREP in the evening before and one litre of MOVIPREP in the early morning of the day of the clinical procedure. Ensure consumption of MOVIPREP 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 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 of MOVIPREP in the evening before and one litre of MOVIPREP in the early morning of the day of the clinical procedure. Ensure consumption of MOVIPREP 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 as well as any other clear fluids has finished at least one hour before the start of the clinical procedure.

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 (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.

Children:
Not recommended in children below 18 years of age, as MOVIPREP has not been studied

in the paediatric population.

4.3 Contraindications

Do not use in patients with known or suspected:

- Intestinal perforation or obstruction due to structural or functional disorder of the gutwall
- Ileus,
- gastric retention
- 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 presence of ascorbate)
- known hypersensitivity to any of the active substances or to any of the excipients

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

4.4 Special warnings and precautions for use

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 or debilitated patients in poor health.

MOVIPREP should be administered with caution in patients with:

- impaired gag reflex, with the possibility of regurgitation or aspiration, or with diminished levels of consciousnessmoderate to 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.

Cases of seizures associated with use of macrogol 3350 with electrolytes for bowel preparation were observed in patients either with or without prior history of seizures. These cases were mostly associated with electrolyte abnormalities such as severe hyponatraemia (see section 4.8). Use caution when prescribing macrogol 3350 with electrolytes in patients with a history of seizures, at increased risk of seizure or at risk of electrolyte disturbance. In case of neurologic symptoms, fluid and electrolyte abnormalities should be corrected.

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.

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 arrhythmia or shifts of fluid/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, 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.

Ischaemic colitis

Post-marketing cases of ischaemic colitis, including serious cases, 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.

Cases of oesophageal rupture (Boerhaave syndrome) associated with excessive vomiting after intake (see section 4.8) of macrogol 3350 with electrolytes for bowel preparation has been reported post-marketing, mostly in elderly patients. Advise patients to stop administration and seek immediate medical assistance if they experience incoercible vomiting and subsequent chest, neck, and abdominal pain, dysphagia, hematemesis or dyspnoea.

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-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.

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.

4.5 Interaction with other medicines and other forms of interaction

The interaction of Moviprep with other medicinal products has not been studied. Theoretically, oral medication taken within one hour (i.e. includes one hour before administration, as well as during administration and one hour after administration) of MOVIPREP, may be flushed from the gastro-intestinal tract unabsorbed.

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

Please refer to section 4.4 for advice on oral contraceptives.

MOVIPREP may have a potential interactive effect when used with starch-based food thickeners. The macrogol ingredient counteracts the thickening effect of starch, effectively liquefying preparations that need to remain thick for people with swallowing problems.

4.6 Fertility, pregnancy and lactation

Fertility

There are no data on the effect of MOVIPREP on fertility

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.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable 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 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, seizure.
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	Oesophageal rupture (Boerhaave syndrome), flatulence, retching.
Hepatobiliary disorders	Uncommon	Abnormal liver function tests.
Skin and subcutaneous tissue disorders	Not known	Allergic skin reactions including angioedema, urticaria, pruritus, rash, erythema.
General disorders and administration site conditions	Very common	Malaise, pyrexia.
	Common	Rigors, thirst, hunger.
	Uncommon	Discomfort.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions via https://pophealth.my.site.com/carmreportnz/s/.

4.9 Overdose

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 Poisons Information Centres:

In Australia, please call 13 11 26
In New Zealand, please call 0800 POISON or 0800 764766

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Osmotically acting laxatives, ATC Code: A06A D

Macrogol 3350, sodium sulfate 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.

5.2 Pharmacokinetic properties

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 15 mg/litre, 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.

Osmotically-acting bowel preparations lead to a copious diarrhoea, resulting in extensive elimination of most of the product via the faeces. They can also lead to changes in electrolyte balance in the body, often with depletion of sodium and potassium, the additional sodium and potassium included in the MOVIPREP formulation help to balance the electrolytes. While some absorption of sodium takes place, the bulk of sodium is expected to be excreted in the faeces as the sodium salts of sulfate and ascorbate, the osmotic active ingredients included in the MOVIPREP composition.

5.3 Preclinical safety data

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

No studies have been carried out on the genotoxicity, carcinogenicity or toxic effect on reproduction with the product.

However, available data on macrogols of relevant size did not identify any potential genotoxicity, carcinogenicity or reproductive toxicity.

Sodium sulfate showed negative results in genotoxicity and reproductive toxicity studies.

Ascorbic acid showed negative results in assessments of genotoxicity and reproductive toxicity and carcinogenicity.

Both sodium chloride and potassium chloride are present at a similar level to normal daily intake from the diet.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Sachets: 24 months (2 years) from manufacture.
Reconstituted solutions: 24 hours

6.4 Special precautions for storage

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

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

6.5 Nature and contents of container

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.

6.6 Special precautions for disposal

No special precautions required.

7 MEDICINE SCHEDULE

Pharmacist-Only Medicine.

8 SPONSOR

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9 DATE OF FIRST APPROVAL
22 May 2008

10 DATE OF REVISION OF THE TEXT
09 09 2025

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
6.1	Change in the composition of the lemon flavouring agent