1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

MOVIPREP powder for oral solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The ingredients of MOVIPREP are contained in two separate sachets.

Each 112 g sachet A of MOVIPREP contains:

Macrogol 3350	100,000 g
Sodium sulphate anhydrous	7,500 g
Sodium chloride	2,691 g
Potassium chloride	1,015 g

Sugar free

Each 11 g sachet B of MOVIPREP contains:

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/litre (of which not more than 56,2 mmol/litre is absorbable)
Chloride	59,8 mmol/litre

Sulphate	52,8 mmol/litre
Ascorbate	29,8 mmol/litre
Potassium	14,2 mmol/litre

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for Oral solution

Sachet A contains a white to off-white free flowing powder with a characteristic lemon odour.

Sachet B contains a white to yellow free flowing powder.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

MOVIPREP is indicated for bowel cleansing prior to any clinical procedures requiring a clean bowel e.g. bowel endoscopy or radiology.

4.2. Posology and method of administration

Adults and elderly

A course of treatment consists of two litres of MOVIPREP. It is strongly recommended that one litre of clear liquid, which may include water, clear soup, fruit juice without pulp, soft drinks, tea and/or coffee without milk is also taken during the course of treatment.

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

The course of treatment can be taken either as:

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

For procedures conducted under general anaesthesia, 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 ensure consumption of MOVIPREP as well as any other clear fluids has finished at least one hour before the start of the clinical procedure when taken as a divided dose and two hours when take as a single dose.

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

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

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

Paediatric population

The safety and efficacy of MOVIPREP in children below 18 years has not yet been

established.

Method of administration

For oral administration.

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 to complete this course.

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.

Reconstituted solution is a clear to hazy, colourless to yellow solution when dissolved in one litre of water.

After reconstitution in water, MOVIPREP consumption may begin immediately or if preferred it may be cooled before use.

4.3. Contraindications

MOVIPREP is contraindicated in:

- Patients with hypersensitivity to macrogol, sodium sulphate anhydrous, sodium chloride, potassium chloride, sodium ascorbate, ascorbic acid or to any of the excipients in MOVIPREP (see section 6.1).
- Gastrointestinal obstruction or perforation.
- Disorders of gastric emptying (e.g. gastroparesis).
- Ileus.
- Phenylketonuria (due to presence of aspartame).

- Glucose-6-phosphate dehydrogenase deficiency (due to presence of ascorbate).
- Toxic megacolon which complicates severe inflammatory conditions of the intestinal tract including Crohn's disease and ulcerative colitis.
- Do not use in unconscious patients.

4.4. Special warnings and precautions for use

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

MOVIPREP should be administered 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 (see section 4.3),
- severe renal insufficiency (creatinine clearance < 30 ml/min),
- cardiac impairment (NYHA grade III or IV),
- those at risk of cardiac arrhythmias, for example those on treatment for cardiovascular disease or who have thyroid disease,
- dehydration,
- severe acute inflammatory bowel disease.

The presence of dehydration should be corrected before the use of MOVIPREP.

The fluid content of MOVIPREP when re-constituted with water 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 observed during administration, especially if this is via the nasogastric route.

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

In debilitated fragile patients, patients with poor health, those with clinically significant renal impairment, dysrhythmias and those at risk of electrolyte imbalance, the medical practitioner should consider performing a baseline and post-treatment electrolyte, renal function test and ECG as appropriate.

There have been rare reports of serious dysrhythmias including atrial fibrillation associated with the use of ionic osmotic laxatives for bowel preparation. These occurred predominantly in patients with underlying cardiac risk factors and electrolyte disturbances.

If patients experience symptoms such as severe bloating, abdominal distention, abdominal pain or any other reaction which makes it difficult to continue the preparation, they may slow down or temporarily stop consuming MOVIPREP and should consult their doctor.

Excipients

MOVIPREP contains 363,2 mmol (8,4 g) sodium per course of treatment. This should be taken into consideration by patients on a controlled sodium diet. Only a proportion of sodium is absorbed.

MOVIPREP contains 28,4 mmol (1,1 g) potassium per course of treatment. This should be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

MOVIPREP contains 0,233 g aspartame in each 112 g sachet A.
Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

4.5. Interaction with other medicines and other forms of interaction

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.

The therapeutic effect of medicines with a narrow therapeutic index or short half-life may be particularly affected.

4.6. Fertility, pregnancy and lactation

Pregnancy

There are no data on the use of MOVIPREP during pregnancy and MOVIPREP should only be used if considered essential by the doctor.

Breastfeeding

There are no data on the use of MOVIPREP during lactation and it should only be used if considered essential by the doctor.

Fertility

There are no data on the effects of MOVIPREP on fertility.

4.7. Effects on ability to drive and use machines

MOVIPREP may cause dizziness. Patients experiencing dizziness should be advised to refrain from driving or using machines.

4.8. Undesirable effects

a) Summary of the safety profile

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 macrogol containing products, allergic reactions including rash, urticaria, pruritus, dyspnoea, angioedema and anaphylaxis are a possibility.

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.

b) Tabulated list of adverse reactions

System organ class	Frequent	Less frequent	Frequency unknown (cannot be estimated from the available data)
Immune system disorders			Allergic reaction including anaphylactic reaction, dyspnoea ,skin reactions
Metabolism and nutrition disorders	Hunger	Hypophosphataemia	Electrolyte disturbances including blood bicarbonate decreased, hyper- and hypo- calcaemia, hypophosphataemia, hypokalaemia and hypornatraemia and changes in the blood chloride levels, dehydration.
Psychiatric disorders	Sleep disorder		
Nervous system disorders	Dizziness	Headache	Convulsions associated with severe hyponatraemia.
Cardiac disorders			Transient increase in blood pressure, arrhythmia, palpitations.
Gastrointestinal disorders	Abdominal pain, nausea, abdominal distension, anal discomfort, vomiting, dyspepsia	Dysphagia	Flatulence, retching.
Hepato-biliary disorders		Abnormal liver function tests.	
Skin and subcutaneous tissue disorders			Allergic skin reactions including angioedema, urticaria, pruritus, rash, erythema.
General disorders and administrative site conditions	Malaise, thirst, rigors, pyrexia, hunger	Discomfort	
Investigations		Decreased blood bicarbonate, decreased blood calcium, hypercalcaemia, blood chloride decreased/increased, decreased blood phosphorous	

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 providers are asked to report any suspected adverse reactions to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

4.9. Overdose

Symptoms

In case of gross accidental overdosage, where diarrhoea is severe, conservative measures are usually sufficient.

Treatment

Generous amounts of fluid, especially fruit juices, should be given. In the rare event of overdose provoking severe metabolic derangement, intravenous rehydration may be used.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Category and class: A 11.5 Medicines acting on the gastrointestinal tract. Laxatives

Pharmacotherapeutic group: Osmotically acting laxatives

ATC code: A06AD

Mechanism of action

Macrogol, sodium sulphate and high doses of ascorbic acid exert an osmotic action in the gut, which induces a laxative effect.

Macrogol 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 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

Absorption

Macrogol is unchanged along the gut. It is virtually unabsorbed from the gastrointestinal tract. Any macrogol 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 absorbed dose. For oral doses between 30 mg and 180 mg an amount of about 70 % to 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.

Elimination

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.

Pre-clinical safety data

Pre-clinical studies provide evidence that macrogol, ascorbic acid and sodium sulphate have no significant systemic toxicity potential.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Acesulfame potassium, aspartame, citral, lemon oil, maltodextrin, vitamin E, xanthan.

Contains sweeteners: Aspartame 0,233 g, acesulfame potassium 0,117 g

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

36 months

6.4. Special precautions for storage

Store at or below 25 °C.

Keep in original packaging until required for use.

Reconstituted solution: Store at or below 25 °C. The solution may be refrigerated (2 °C to 8 °C). Keep the solution covered.

6.5. Nature and contents of container

Sachet A: 112 g of powder is packed in a sachet made from laminate consisting of low density polyethylene, aluminium and paper.

Sachet B: 11 g of powder is packed in a sachet made from a laminate consisting of low

density polyethylene, aluminium and paper.

MOVIPREP contains four printed paper sachets (2 of sachet A and 2 of sachet B). One sachet A and one sachet B are packed together in a transparent polypropylene pouch; both are white sachets with blue print. One pack of MOVIPREP contains two of these pouches packed into an outer carton, white in colour with blue print.

MOVIPREP is available in pack sizes of 1, 10, 40, 80, 160 or 320 packs of a single treatment.

Not all packs or pack sizes may be marketed.

6.6. Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

8. REGISTRATION NUMBER

42/11.5/0407

9. DATE OF FIRST AUTHORISATION

30 September 2011

10. DATE OF REVISION OF TEXT

31 July 2021

Die Afrikaanse Professionele Inligting is op versoek beskikbaar. Mediese Blitslyn: 0800 118 088.

Namibia: NS2 12/11.5/0221

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