1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

MOVICOL 13,8108 g powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet of 13,8108 g of MOVICOL powder contains:

Macrogol (PEG) 3350	13,125 g
Sodium bicarbonate	178,5 mg
Sodium chloride	350,7 mg
Potassium chloride	46,6 mg

The content of electrolyte ions per sachet when made up to 125 ml of solution is as follows:

Sodium	65 mmol/L
Potassium	5,4 mmol/L
Chloride	53 mmol/L
Bicarbonate	17 mmol/L

Contains sweetener: Acesulfame potassium 10 mg

Sugar free

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder for oral solution.

MOVICOL is a white, free-flowing, crystalline powder with a flavour and odour of lemon and lime. The reconstituted solution is a colourless, slightly hazy solution when compared with an equal volume of water.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

MOVICOL is indicated in adults and adolescents for the treatment of chronic constipation.

4.2. Posology and method of administration

Posology

Adults

Adults, adolescents and the elderly: 1 to 3 sachets daily in divided doses, according to individual response, each sachet reconstituted in 125 ml water and taken orally.

Children (below 12 years old): not recommended.

No dosage change is needed for patients with renal insufficiency.

A course of treatment with MOVICOL does not normally exceed two weeks, although this can be repeated if required.

Extended use may be necessary in the care of patients with severe chronic or resistant constipation, secondary to multiple sclerosis or Parkinson's disease, or induced by regular constipating medicine, in particular opioids and antimuscarinics.

For extended use, the dose can be adjusted down to 1 or 2 sachets daily, in divided doses, each reconstituted with 125 ml water and taken orally.

Special populations

Elderly population

1 to 3 sachets daily in divided doses, according to individual response.

Renal impairment

No dosage change is necessary for the treatment of constipation (see section 4.4).

Paediatric population

Not recommended for children below 12 years old.

Method of administration

For oral administration

4.3. Contraindications

MOVICOL is contraindicated in:

- Patients with hypersensitivity to macrogol (PEG), sodium bicarbonate, sodium chloride, potassium chloride or to any of the excipients in MOVICOL (see section 6.1).
- Patients with intestinal perforation or obstruction due to structural or functional disorder of the gut wall, ileus, gastric retention, peptic ulceration, and severe inflammatory conditions of the intestinal tract, such as Crohn's disease, ulcerative colitis and toxic megacolon.
- Patients under 12 years of age.

4.4. Special warnings and precautions for use

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

MOVICOL should not be used in the presence of abdominal pain, nausea or vomiting.

MOVICOL should not be used continuously unless directed by a doctor. Frequent or prolonged use of laxatives may result in dependence and loss of normal bowel function.

If patients develop any symptoms indicating shifts of fluids/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure) MOVICOL should be stopped immediately and electrolytes measured and any abnormality should be treated appropriately.

If there is a sudden change in bowel habits that has persisted for a period greater than 2 weeks, a medical practitioner should be consulted.

Rectal bleeding or failure to have a bowel movement after use of MOVICOL may indicate a serious condition. MOVICOL should be discontinued and medical advice obtained.

Adverse drug reactions are possible (see section 4.8.) If patients develop any symptoms indicating shifts of fluids/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure) MOVICOL should be stopped immediately and electrolytes measured, and any abnormality should be treated appropriately.

The absorption of other medicines could transiently be reduced due to a decrease in gastrointestinal transit rate induced by MOVICOL (see section 4.5).

Reactions related to the gastrointestinal tract occur most commonly. These reactions may occur as a consequence of expansion of the contents of the gastrointestinal tract, and an increase in

motility due to the pharmacologic effects of MOVICOL (see section 4.8). Diarrhoea usually responds to dose reduction.

MOVICOL contains 8,125 mmol sodium per dose, equivalent to 9,3 % of the WHO recommended maximum daily intake for sodium. The maximum daily dose of this product is equivalent to 28 % of the WHO recommended maximum daily intake for sodium. MOVICOL is considered high in sodium. This should be particularly taken into account for those on a low salt diet.

4.5. Interaction with other medicines and other forms of interaction

Macrogol (PEG), as in MOVICOL, raises the solubility of medicines that are soluble in alcohol and relatively insoluble in water.

There is a possibility that the absorption of other medicines could be transiently reduced during use with MOVICOL (see section 4.4). There have been reports of decreased efficacy with some concomitantly administered medicines, e.g. anti-epileptics.

4.6. Fertility, pregnancy and lactation

Pregnancy

There are limited amount of data from the use of MOVICOL in pregnant women. Clinically, no effects during pregnancy are anticipated, since systemic exposure to macrogol 3350 (PEG), as in MOVICOL, is negligible.

MOVICOL can be used during pregnancy.

Breastfeeding

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breastfeeding woman to macrogol (PEG), as in MOVICOL, is negligible.

MOVICOL can be used during breastfeeding.

Fertility

There are no data on the effects of MOVICOL on fertility in humans. There were no effects on fertility in studies in male and female rats.

4.7. Effects on ability to drive and use machines

MOVICOL has no influence on the ability to drive and use machines.

Patients should not drive, use machinery or perform any tasks that require concentration until they are certain that MOVICOL does not adversely affect their ability to do so safely (see section 4.8).

4.8. Undesirable effects

a) Summary of the safety profile

Reactions related to the gastrointestinal tract occur most commonly. These reactions may occur as a consequence of expansion of the contents of the gastrointestinal tract, and an increase in motility due to the pharmacologic effects of MOVICOL. Mild diarrhoea usually responds to dose reduction.

b) Tabulated list of adverse reactions

System organ class	**Frequency unknown**
Immune system disorders	Allergic reactions (anaphylactic reactions, dyspnoea and skin reactions)
Metabolism and nutrition disorders	Electrolyte disturbances (hyperkalaemia,hypokalaemia)

Nervous system disorders	Headache
Gastrointestinal disorders	Abdominal pain, abdominal cramps, diarrhoea, vomiting, nausea, dyspepsia, abdominal distension, borborygmi, flatulence, anorectal discomfort
Skin and subcutaneous tissue disorders	Allergic skin reactions (angioedema, urticaria, pruritus, rash, erythema)
General disorders and administrative site conditions	Peripheral oedema

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

- Extensive fluid loss by diarrhoea or vomiting
- Severe abdominal pain or distension

Treatment

In the case of gross accidental overdosage, extensive fluid loss by diarrhoea or vomiting may require correction with generous amounts of fluid and electrolytes. Severe abdominal pain or distension, associated with overdosage, can be treated by nasogastric aspiration.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

MOVICOL, an iso-osmotic laxative, is a combination of macrogol (polyethylene glycol (PEG)) and electrolytes.

Macrogols are long linear polymers, also known as polyethylene glycols.

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

Pharmacotherapeutic group: Osmotically acting laxatives

ATC code: A06AD15

Mechanism of action

Macrogol (PEG) acts by virtue of its osmotic action in the gut, which induces a laxative effect. Macrogol (PEG)increases the stool volume, which triggers colon motility via neuromuscular pathways. The physiological consequence is an improved propulsive colonic transportation of the softened stools and a facilitation of defaecation. Electrolytes combined with macrogol (PEG) are exchanged across the intestinal barrier (mucosa) with serum electrolytes and excreted in faecal water without net gain or loss of sodium, potassium and water.

Clinical studies on the use of MOVICOL in chronic constipation have shown that the dose needed to produce normal formed stools tends to reduce over time. Many patients respond to between 1 and 2 sachets of powdered MOVICOL per day, but this dose should be adjusted depending on individual response.

5.2. Pharmacokinetic properties

Absorption

Macrogol (PEG) is unchanged along the gut. It is virtually unabsorbed from the gastrointestinal tract. The laxative action of polyethylene glycol has a time course which will vary according to the severity of the constipation being treated.

Elimination

Any macrogol (PEG) that is absorbed is excreted via the urine.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Acacia solids, acesulfame potassium, citral citric acid, lemon oil, lime oil, maltodextrin, water

6.2. Incompatibilities

Not applicable

6.3. Shelf life

36 months

6.4. Special precautions for storage

Sachet: Store at or below 25 °C.

Reconstituted solution: Store covered in a refrigerator at 2 °C to 8 °C. Discard any solution not used within 24 hours.

Keep in original packaging until required for use.

6.5. Nature and contents of container

MOVICOL is filled into rectangular, 4-layer laminated sachets with label printing on both sides of the sachet. The laminate is composed of paper, aluminium foil and low density polyethylene.

Sachets are sealed together in pairs with a perforated strip between them to allow for the separation of each sachet. Each carton contains 2, 6, 8, 10, 20, 30, 60, 100 sachets that are packed into a printed cardboard carton, with a leaflet.

Not all pack sizes are necessarily marketed.

6.6. Special precautions for disposal

No special requirements

7. HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

8. REGISTRATION NUMBER

31/11.5/0123

9. DATE OF FIRST AUTHORISATION

Date of registration: 21 February 1997

10. DATE OF REVISION OF TEXT

03 August 2021

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

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