1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

MOVICOL 13,8108 g powder

Macrogol 3350

Sodium bicarbonate

Sodium chloride

Potassium chloride

Sugar free

Read all of this leaflet carefully because it contains important information for you

MOVICOL is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use MOVICOL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share MOVICOL with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after a few days.

What is in this leaflet

1. What MOVICOL is and what it is used for
2. What you need to know before you take MOVICOL
3. How to take MOVICOL
4. Possible side effects
5. How to store MOVICOL

6. Contents of the pack and other information

1. WHAT MOVICOL is and what it is used for

MOVICOL belongs to a group of medicines called laxatives for the treatment of constipation in adults, adolescents and elderly. It is not recommended for children below 12 years of age. MOVICOL helps you to have a comfortable bowel movement even if you have been constipated for a long time.

2. What you need to know before you take MOVICOL

Do not take MOVICOL

- if you are hypersensitive (allergic) to macrogol, sodium chloride, sodium bicarbonate, potassium chloride or any of the other ingredients of MOVICOL.
- if you have a blockage in your gut (symptoms may include severe stomach pain, nausea, vomiting and an inability to pass wind or stools).
- if you have a perforated (ruptured) gut wall (with symptoms such as severe stomach pain and tenderness).
- if you have ileus (paralysis of the intestines with symptoms such as stomach cramps, bloating, nausea, vomiting, constipation, difficulty passing wind and difficulty tolerating a normal diet).
- if you have gastric retention (symptoms generally include nausea, vomiting, bloating, and upper abdominal discomfort).
- if you have peptic ulceration (a sore that develops on the lining of the oesophagus, stomach or small intestine with symptoms such as upper abdominal pain).
- if you have severe inflammatory bowel disease like ulcerative colitis (chronic disease affecting the large bowel), Crohn's disease (inflammation of last part of small bowel) or toxic megacolon (potentially lethal complication of inflammatory bowel disease or infectious colitis that is characterized by an abnormal dilation of the large intestine).

- if you are under 12 years of age.

Warnings and precautions

Take special care with MOVICOL:

- MOVICOL does not replace regular fluid intake and adequate fluid intake must be maintained.
- if you develop any of the following symptoms; swelling, shortness of breath, increasing tiredness, dehydration or heart failure. MOVICOL should be stopped immediately.
- if you are taking other medicines as they might not work as well.
- as stomach problems occur most commonly, and frequent/loose watery stools (diarrhoea) usually responds to dose reduction.
- if you are on a low salt diet as MOVICOL contains salt.
- if patients develop any symptoms indicating shifts of fluids/electrolytes.
- if you have stomach ache, feel nauseous (feel sick) or are vomiting (being sick).
- consult your doctor before using MOVICOL if you notice a sudden change in your bowel habits that persists for a period longer than 2 weeks.
- consult your doctor if you experience rectal bleeding or do not have a bowel movement after using MOVICOL.
- do not use MOVICOL frequently or for long periods as this may cause dependence and a loss of normal bowel function.

Children and adolescent

Not recommended for children below 12 years old.

Other medicines and MOVICOL

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- anti-epileptics. medicines used to treat epilepsy.
- 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 reduced during use with MOVICOL and might not work as well.

Taking MOVICOL with food and drink

MOVICOL contains sodium

Talk to your doctor or pharmacist if you need 3 or more sachets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

MOVICOL contains 186,87 mg sodium (main component of cooking/table salt) per sachet.

This is equivalent to 9,3 % of the recommended maximum daily dietary intake of sodium for an adult.

Pregnancy, breastfeeding and fertility

MOVICOL can be taken during pregnancy and whilst breastfeeding.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving and using machines

MOVICOL is not expected to influence your ability to drive. However, you should not drive, use machinery or perform any tasks that require concentration until you are certain that MOVICOL does not adversely affect your ability to do so safely (see section 4).

It is not always possible to predict to what extent MOVICOL may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which MOVICOL affects you (see section 4).

3. How to take MOVICOL

Do not share medicines prescribed for you with any other person.

Always take MOVICOL exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose is:

Adults, adolescents and the elderly: 1 sachet 1 to 3 times a day.

For extended use, 1 or 2 sachets a day.

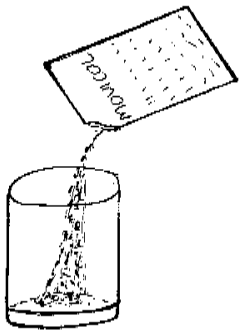
Children (below 12 years old): not recommended.

Your doctor will tell you how long your treatment with MOVICOL will last. Do not stop treatment early. If you have the impression that the effect of MOVICOL is too strong or too weak, tell your doctor or pharmacist.

Instructions for use:

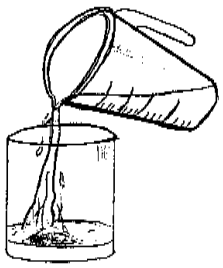
1. Open one sachet and pour the contents of one sachet of MOVICOL into a glass.

1.



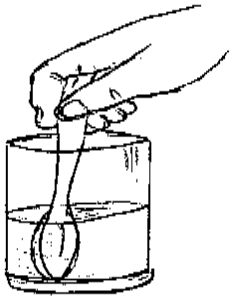
2. Add 125 ml (½ glass) of water.

2.



3. Stir the mixture well until all the powder has dissolved and the MOVICOL solution is clear or slightly hazy.

3.



4. Drink the solution.

If you like you can add a flavour such as orange squash to the drink.

Duration of treatment

Treatment with MOVICOL usually lasts for about 2 weeks.

If your constipation is caused by an illness such as Parkinson's disease or multiple sclerosis

(MS), or if you take medicines that cause constipation your doctor may recommend that you take MOVICOL for longer than 2 weeks.

If you take more MOVICOL than you should

Stop taking MOVICOL until the diarrhoea clears. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take MOVICOL

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

MOVICOL can have side effects.

Not all side effects reported for MOVICOL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MOVICOL, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking MOVICOL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MOVICOL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- hyperkalaemia (too much potassium in the blood which can cause abnormal heart rhythm); hypokalaemia (low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Side effects with an unknown frequency

- headache;
- stomach pain; stomach cramps; diarrhoea (frequent/loose watery stools); vomiting (being sick); nausea (feeling sick); dyspepsia (heartburn; indigestion); feeling bloated, stomach rumbles, flatulence, anus and rectum discomfort,
- peripheral oedema (accumulation of fluid causing swelling usually in the lower limbs).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

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

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of MOVICOL.

5. How to store MOVICOL

Store all medicines out of reach of children.

Store at or below 25 °C.

Once you have made up MOVICOL in water to form the reconstituted solution, and if you cannot drink it straight away, keep it covered and store it in the fridge (2 °C to 8 °C). Throw away any solution not used within a 24-hour period.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date on the sachet and carton.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

The active substances are 13,125 g of macrogol (PEG) 3350, 178,5 mg of sodium bicarbonate, 350,7 mg of sodium chloride and 46,6 of potassium chloride.

When MOVICOL powder is made into a drink with 125 ml of water each sachet gives the equivalent of:

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

The other ingredients are acacia solids, acesulfame potassium, citral citric acid, lemon oil, lime oil, maltodextrin, water.

Contains sweetener: Acesulfame potassium 10 mg

Sugar free

What MOVICOL looks like and contents of the pack

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.

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.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912 (South Africa)

This leaflet was last revised in

03 August 2021

REGISTRATION NUMBER

31/11.5/0123

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

ZA_MOVIPOW_2108_00