

Package leaflet: information for the patient

MOVICOL® 13.8 g sachet, powder for oral solution
macrogol 3350, sodium chloride, sodium bicarbonate, potassium chloride

Read carefully the entire leaflet before you use this medicine because it contains important information for you. Use

this medicine medication always exactly as in this leaflet described or as your doctor, pharmacist or nurse you that has told.

- Store this leaflet. Maybe you need it later again needed.
- Do you still questions? Then contact your pharmacist.
- Do you experience one of the side effects listed in section 4 are? Or do you experience a side effect that is not in this leaflet ? Then contact your doctor, your doctor, pharmacist or nurse.
- Does your complaint not lessen, or does it even worsen? Then contact your doctor.

Contents of this leaflet:

1. What is Movicol and what is it used for used?
2. When should you not use Movicol not use or must you be extra careful with it be?
3. How used do you use Movicol?
4. Possible side effects
5. How do you store Movicol?
6. Contents of the package and other information

1. What is Movicol and what is it used for?

The name of this medicine is Movicol 13.8 g sachet, powder for drink. It is a laxative for the treatment of constipation in adults, adolescents and elderly. The use in children under 12 years is not recommended.

Movicol helps you to have an easier bowel movement to make even if you are already long time constipated . Movicol is also effective in very severe constipation, fecal impaction called.

2. When may you not use Movicol not use or must you be extra careful with it be?

Do not take Movicol not if your doctor has said has has that you:

- a internal obstruction have (bowel obstruction, ileus)
- a perforated intestinal wall have
- a severe inflammatory disease of the intestine have, such as colitis ulcerosa, disease of Crohn or toxic megacolon
- allergic are to one of the substances in this medicine. These substances can you find in section 6 of this leaflet.

When should you be extra careful with Movicol? When using Movicol you must be careful sufficient fluid remain take. The Movicol solution is not a replacement for the regular fluid intake.

Heart diseases

Follow the special instructions for section 3 if you take Movicol takes for faecal impaction.

Do you still other medications?

Do you besides Movicol still other medicines, have you that recently done or are you this perhaps soon do ?Tell that then then your doctor or pharmacist.

Some medications, for example anti-epileptics, may possibly less effectively work during the use of Movicol.

You may not take other medications by mouth together with Movicol and for one hour before and one hour after taking Movicol.

If you liquids need to thicken to these safely to be able to swallow, keep in mind that Movicol may counteract the effect of thickening agents can counteract can counteract.

Pregnancy and breastfeeding

Movicol can during the pregnancy and breastfeeding be used . Are you pregnant ,do you think you pregnant to tea are, do you pregnant become or are you breastfeeding? Then contact your doctor or pharmacist before you this medicine use.

Driving ability and the use of machines

Movicol has no effect on your ability to drive or operate machines to use ..

contains sodium sodium

Contact your doctor or pharmacist if you long-term 3 or more sachets per day need have, especially if you are advised a low-salt (low-sodium) diet to follow.

Movicol contains 186.87 mg sodium (an important component of table salt/table salt) per sachet. This corresponds to 9.3% of the recommended maximum daily amount of sodium in the diet for an adult.

3. How do you use Movicol?

This medicine can at any time be taken , with or without food ..

contents of each sachet in 125 ml of water. Then drink it. Constipation

Constipation:

dose of Movicol is 1 sachet dissolved resolved in 125 ml water.

Take 1 to 3 times per day a sachet depending on the severity of your constipation.

Fecal impaction:

Before u Movicol takes for fecal impaction must there confirmed be that you this condition have.

The dose for the treatment of fecal impaction is 8 sachets Movicol per day. Each sachet must be dissolved in 125 ml water. The 8 sachets must within the 6 hours be taken become and this, if necessary, up to 3 days long. If you have a heart problem , you maynot take more than 2 sachets in one hour take.

How to mix:

Open the sachet and pour the contents of it into a glass. Add approximately 125 ml water to the glass add. Stir well until all the powder dissolved is and the Movicol solution clear or slightly cloudy is, and drink then the solution on. If you take Movicol take for faecal impaction, it may be easier to dissolve 8 sachets in one liter of water. Duration of the treatment liter of water.

Duration of the treatment:

Constipation:

A treatment with Movicol usually lasts about 2 2 . If you need to take Movicol longer , consult your doctor. If your doctor recommends it. constipation caused is by a disease such as the disease of Parkinson's or multiple sclerosis (MS), or if you medications take that constipation cause, can your doctor recommend to take Movicol longer than 2 weeks to take. If you need to take Movicol longer must take, then go to your doctor.

The dosage for long-term use can usually be reduced to 1 or 2 sachets per day.

Faecal impaction:

A treatment with Movicol can take up to 3 days last.

Have you taken too much of Movicol ?You

might experience excessive diarrhea which can lead to dehydration . In. In this case you should you to stop taking taking Movicol and sufficiently to drink. If you are concerned , please contact your doctor or doctor or pharmacist.

When you take too much of Movicol have taken, contact immediately your doctor, pharmacist or the Poison Center (070/245.245). If you

forgot forgotten Movicol in to take?

Take the dosage as soon as you think of it.

4. Possible side effects

Like any medicine can also this medication side effects have. Not everyone experiences with it ..

it your doctor immediately and stop taking Movicol intake of Movicol if you:

A severe allergic reaction gets that difficulties with breathing, or swelling of the face, the lips, tongue or throat causes.

Other side effects are:

Allergic reactions that a skin rash, itching, redness of the skin, or hives, swollen hands, feet or ankles and headache can cause, high or low levels potassium in the blood.

Sometimes can you a indigestion (mild disorder of the digestion) have, abdominal pain or rumbling in the abdomen. You may also feel bloated feeling have, last have from flatulence, nauseous are or vomiting. You can also pain in the anus (buttocks) experience and you can mild diarrhea have at the start of the intake of Movicol. These side effects usually improve as you reduce the to take amount Movicol.

The reporting of side effects

Do you experience side effects, please contact your doctor, pharmacist or nurse. This applies also to side effects that not in this leaflet are. You can side effects also report via:

Federal Agency for Medicines and Health Products

www.fagg.be

Department Vigilance

Website: www.eenbijwerkingmelden.be

e-mail: adr@fagg-afmps.be

By reporting side effects to report, you help us to obtain more information about the safety of from this medicine.

5. How do you store Movicol?

Keep out of sight and reach of children ..

Movicol after the expiry date the expiry date. You can find it on the sachet and the box. There is a month and a year. The last day of the month is the expiry date.

For this medicine there are no special storage conditions.

If you have dissolved Movicol in water and and you can it not immediately drink, store it then covered and in the refrigerator (2°C - 8°C). Discard any solution that not within de 6 hour used was away.

Rinse medicines not through the sink or the toilet and throw them not in the trash. Ask your pharmacist what to do with medicines you should do not use anymore. If you medicines in the correct way dispose, they are one correct way destroyed and come they not into the environment end up.

6. Contents of the package and other information

Which substances are in Movicol?

Each sachet of 13.8 g Movicol contains the following:

Macrogol 3350	13.125 g
Sodium chloride	0.3507 g
Sodium bicarbonate	0.1785 g
Potassium chloride	0.0466 g

Movicol also contains lime- and lemon flavor and acesulfame potassium as sweetener.

Lemon- and lime flavor contains the following ingredients: arabic gum, maltodextrin, lime oil, lemon oil, citral, citric acid and water.

Once the solution prepared is with 125 ml water, provides each sachet the equivalent of:

Sodium	65 millimol/liter
Chloride	53 millimol/liter
Potassium	5.4 millimol/liter
Bicarbonate	17 millimol/liter

What does Movicol look like and what is in a package?

Movicol is available in rectangular sachets and tube-shaped sachets. Movicol is a white powder.

Movicol is available in boxes of 2, 6, 8, 10, 20, 30, 50, 60 or 100 sachets. Not all mentioned sachets and pack sizes are on the market placed.

Holder of the authorization for placing on the market bring:

Norgine NV, Philipssite 5 bus 1, 3001 Heverlee

Manufacturer:

Laboratoires Macors, Rue des Caillottes, ZI La Plaine des Isles, 89000 Auxerre, France

Or

Sophartex, 21 Rue du Pressoir, 28500 Vernouillet, France

Or

Norgine B.V., Antonio Vivaldistraat 150, 1083 HP Amsterdam, Netherlands Or

Recipharm Höganäs AB, Sporthallsvägen 6, Höganäs, 263 35, Sweden

Or

Delpharm Orleans, 5 avenue de Concyr, ORLEANS CEDEX 2, 45071, France

This medication is registered in member states of the European Economic Area under the following names:

Belgium	MOVICOL
Germany	Macrogol Norgine Lemon and Lime flavor Powder for Manufacture of a solution for oral use
Finland	MOVICOL
Ireland	MOVICOL
Italy	MOVICOL 13.8 g powder for oral solution
Austria	MOVICOL powder
Portugal	MOVICOL
Spain	MOVICOL
Sweden	MOVICOL

Number of the license for placing on the market : BE180196Method of delivery

: Freedelivery This

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