

Macrogol 4000 (10.7 g) with excipients

Sachet

TRADE NAME

For the treatment of constipation

Powder for oral solution



Expiry date:



Batch number:



25 °C

Do not store above 25 ° C!

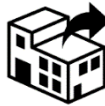


Please follow instructions for use!



Manufacturer:

Fairpharm Vertriebs GmbH
Georg-Kalb-Straße 5
82049 Pullach i. Isartal
Germany
www.fairpharm.com



Distributor: company name, address,
website with product information



0197



Medical Device

Macrogol 4000 (10.7 g) with excipients

Back:

Composition:

1 sachet with 10.7 g of powder contains:

Macrogol (PEG) 4000 10 g

Other ingredients:

Magnesium citrate, citric acid, calcium citrate, acesulfame K, lemon flavour, potassium chloride, silicon dioxide

Administration:

The content of one sachet is dissolved in 125 ml (1/8 litre) of water and then drunk.

Adults, adolescents and elderly patients:

Unless otherwise prescribed by the doctor, the usual dose is:

1 – 3 sachets daily dissolved and drunk.

When taking it for a longer period of time, the dose may be reduced to 1 to 2 sachets.

Keep out of the reach of children!

Macrogol 4000 (10.7 g) with excipients

Carton box

TRADE NAME

10 sachets, each containing 10.7 g of powder for oral solution.

Composition:

1 sachet with 10.7 g of powder contains 10 g of macrogol (PEG) 4000.

Other ingredients:

Magnesium citrate, citric acid, calcium citrate, acesulfame K, lemon flavour, potassium chloride, silicon dioxide



batch number:



Expiry date:



Do not store above 25 ° C!



Please follow instructions for use!

Keep out of the reach of children.



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Medical Device



UDI

Macrogol 4000 (10.7 g) with excipients

Instructions for use:

TRADE NAME

For the treatment of (chronic) constipation.

Macrogol 4000 Powder for oral solution



Please read these instructions for use carefully because they include important information you have to consider before using this product.

This medical device is available without prescription.

For the best results, always take *TRADE NAME* exactly as described in this leaflet.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If your symptoms worsen or do not get better after 4 days, you should consult a physician in any case.
- If any of the given side effects bothers you notably or if you notice any side effects that are not mentioned in this leaflet, please inform your physician or pharmacist.

In this leaflet:

1. What is *TRADE NAME* and what is it used for?
2. Before you take *TRADE NAME*
3. How to take *TRADE NAME*
4. Possible side effects
5. How to store *TRADE NAME* and how long is it stable?
6. Further information

1. What is *TRADE NAME* and what is it used for?

TRADE NAME (medical device) is a laxative.

TRADE NAME is used for the treatment of (chronic) constipation.

2. Before you take *TRADE NAME*

Do not take *TRADE NAME* in case of:

- Hypersensitivity (allergic reaction) to the active substance (please see composition)
- Digestive perforation or risk of digestive perforation
- Intestinal obstruction as a result of a structural or functional disruption of the gut wall
- Ileus or suspicion of intestinal obstruction
- Severe inflammatory bowel disease (such as Crohn's disease, ulcerative colitis) or enlarged colon as a complication of an intestinal ulcer (toxic megacolon)
- Painful abdominal syndromes of indeterminate cause
- An illness of the intestinal tract and the large intestine such as occlusive or subocclusive syndrome

Take special care before initiation of treatment when symptoms occur that indicate an imbalance of the water-electrolyte metabolism, i.e. oedema, respiratory distress, overtiredness, loss of body fluid (dehydration) or cardiac failure.

If you notice any of the above signs or symptoms, you should stop taking *TRADE NAME* and consult a doctor immediately. He will measure your electrolytes and initiate the necessary treatment.

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Use in children

There is not enough experience with the use of *TRADE NAME* in children. Therefore this product is not to be used by children under 12 years of age.

Pregnancy and breast-feeding

There is not enough experience with the use of *TRADE NAME* during pregnancy and breast-feeding. If you are pregnant or breast-feeding, ask your doctor before taking *TRADE NAME*.

Use in diabetics

TRADE NAME is sugar-free and suitable for diabetics. The content of one sachet contains 0.00 carbohydrate units.

Ability to drive and use machines

No special precautions are required.

Taking *TRADE NAME* with other medication

Reports about interactions with other medication are unknown. But *TRADE NAME* increases the solubility of substances that are soluble in alcohol and sparingly soluble in water. There is a theoretical possibility that the resorption of such active substances may temporarily be reduced.

If you need to thicken fluids in order to swallow them safely, *TRADE NAME* may counteract the effect of the thickener.

3. How to take *TRADE NAME*

Always take *TRADE NAME* exactly as described in this leaflet. Check with your doctor or pharmacist if you are not sure. If not prescribed otherwise by your doctor:

Adults, adolescents and elderly patients

Dissolve 1 to 3 times daily the content of one sachet in 125 ml of water and drink the solution. When taking it for a longer period of time, the dose may be reduced to 1 to 2 sachets daily.

Patients with limited kidney function

No dosage change is required.

Duration of treatment

TRADE NAME may be taken for a longer period of time. The treatment of constipation with a laxative should be supportive along with a healthy style of life and nutrition.

A fairly long-term application may be necessary in case of severe chronic or persistent (refractory) constipation. This may occur along with diseases like multiple sclerosis or morbus Parkinson or when taking medication facilitating constipation such as strong acting pain relievers (opioids) or anti-Parkinson medication (anticholinergics).

You can take it at any time of the day independent from meals. *TRADE NAME* may be taken for a longer period of time (at most 4 weeks). Please note that it usually takes 24 - 48 hours to work. If it does not get better after 4 days, you should consult a physician in any case.

Administration

Dissolve the content of one sachet in a glass with 125 ml of drinking water and drink all of it. If you take other medication, it is recommended to take it with at least 2 hours delay.

Please consult your physician or pharmacist if you have the impression that the effect of *TRADE NAME* is too strong or too weak.

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If you have taken more than the recommended dose, side effects may be more intense. These will typically subside again soon. In case of strong pain, bloating or heavy diarrhoea please consult your physician!

If you forgot to take *TRADE NAME*, do not take a double dose, but continue with the dosing as planned.

Should you have any further questions of how to take *TRADE NAME*, please ask your physician or pharmacist.

4. Possible side effects

As a result of the extension of the content of the gut after having taken *TRADE NAME* a feeling of fullness, bloating, additional sounds from the intestines (borborygm), stomach pain, nausea, vomiting and diarrhoea may occur. In rare cases there may be hypersensitivity reactions, for example severe allergic reactions with difficulty breathing (anaphylactic shock), urticaria (skin rash, itchy wheals), angioedema (swelling of the skin, subcutaneous tissue or mucosa). In case of hypersensitivity reactions the treatment must be terminated.

Please inform your physician or pharmacist if one of the given side effects bothers you notably or if you notice any side effects that are not mentioned in this leaflet.

You should report any serious incident that has occurred in relation to this product to the manufacturer and to *contact details of the competent authority in the country where the product is distributed*.

5. How to store *TRADE NAME* and how long is it stable?

Keep out of the reach of children.

Do not use *TRADE NAME* after the expiry date, which is printed on the carton. The expiry date refers to the last date of that month. Opened or damaged sachets must not be used.



Do not store above 25°C.



Expiry date

Macrogol 4000 (10.7 g) with excipients

6. Further information

What does *TRADE NAME* contain?

The active substance is macrogol 4000.

1 sachet contains 10 g of macrogol (PEG) 4000

The other ingredients are: magnesium citrate, citric acid, calcium citrate, acesulfame K, lemon flavour, potassium chloride, silicon dioxide

TRADE NAME is available in a pack size of 20 sachets.

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Medical Device

Date of information: September 2025