

Macrogol 4000 (10 g) without excipients

Sachet

<Trade name>

Macrogol 4000 Powder for oral solution

<For countries without any local requirement to limit the duration of use:>

Symptomatic treatment of occasional or chronic constipation

<For countries with local requirement to limit the duration of use:>

Symptomatic treatment of occasional constipation

- Softening of hard stools



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



0197



Medical Device



Distributor: *company name, address, website with product information*

Composition:

1 sachet with 10 g of powder contains:

Macrogol 4000 (10 g) without excipients

Macrogol 4000 10 g (no excipients)

How to take <Trade name>:**Adults and children aged 8 years and over:**

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

1 – 2 sachets daily dissolved in liquid, preferably taken as a single dose in the morning.

Children under 8 years should not use this product since other products are available that are better suited.

Within the dose recommendation the dose can be adjusted to your individual needs. It may range from one sachet every other day to two sachets per day. The right dose is the lowest dose to produce regular soft stools.

Keep out of the reach and sight of children!

Macrogol 4000 (10 g) without excipients

Carton box

<trade name>

Macrogol 4000 Powder for oral solution

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

Composition:

1 sachet with 10 g of powder contains 10 g of macrogol 4000 (no excipients).

<For countries without any local requirement to limit the duration of use:>

For the symptomatic treatment of occasional or chronic constipation and the softening of hard stools

<For countries with local requirement to limit the duration of use:>

For the symptomatic treatment of occasional constipation and the softening of hard stools



UDI



batch number



Expiry date:



Do not store above 25 ° C!



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Macrogol 4000 (10 g) without excipients

Instructions for use:

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Macrogol 4000 (10 g) without excipients

Instructions for use

<Trade name>

Macrogol 4000 Powder for oral solution



Please read these instructions for use carefully because they contain important information you have to consider before using this product. If you are not sure or if you have any further questions, ask your physician or pharmacist.

<For countries without any local requirement to limit the duration of use:>

<TRADE NAME> is a medical device for the symptomatic treatment of occasional or chronic constipation and the softening of hard stools in constipation.

<For countries with local requirement to limit the duration of use:>

<TRADE NAME> is a medical device for the symptomatic treatment of occasional constipation and the softening of hard stools in constipation.

Keep this leaflet. You may want to read it again.

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>
6. Further information

1. What is <TRADE NAME> and what is it used for

The ingredient of <TRADE NAME> is macrogol 4000. Macrogol 4000 has a high water-binding capacity and serves as a carrier for the liquid (water), Macrogol transports water directly into the colon. There, the hardened stool is hydrated, softened and stool volume increases. This leads to increased bowel movement and eases defecation. Macrogol 4000 has a purely physical mode of action; it is not absorbed by the body and excreted unchanged.

<TRADE NAME> is used for:

<For countries without any local requirement to limit the duration of use:>

- Symptomatic treatment of occasional or chronic constipation
- Softening of hard stools

<For countries with local requirement to limit the duration of use:>

- Symptomatic treatment of occasional constipation
- Softening of hard stools

Macrogol 4000 (10 g) without excipients

2. Before you take <TRADE NAME>

Do not take <TRADE NAME> in case of:

- Hypersensitivity to the active substance (please see composition)
- Severe inflammatory bowel disease (such as ulcerative colitis, Crohn's disease) or toxic megacolon
- Digestive perforation or risk of digestive perforation
- Ileus or suspicion of intestinal obstruction or symptomatic stenosis
- Painful abdominal syndromes of indeterminate cause

Do not take <TRADE NAME> if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking <TRADE NAME>.

Take special care

As with all laxatives, an organic disorder should have been ruled out before initiation of treatment. Without investigating the cause of constipation, <TRADE NAME> should not be taken on a continuous daily basis for an extended period of time. You should seek medical advice in case of persistent abdominal pain.

In case of diarrhoea, caution should be exercised in patients who are prone to a disturbance of water or electrolyte balance (e.g. elderly, patients with impaired hepatic or renal function or patients taking diuretics) and electrolyte control should be considered.

Allergic conditions (such as anaphylactic shock, anaphylactic reaction, angioedema, urticaria, rash and hypersensitivity) have been reported in patients taking products containing macrogol.

If you notice any of the above signs or symptoms, you should stop taking <TRADE NAME> and consult a doctor immediately.

Pregnancy and breast-feeding

<TRADE NAME> can be taken during pregnancy or breast-feeding since absorption of macrogol 4000 is negligible and for that reason no effects are anticipated. However, if you are pregnant or breast-feeding it is advisable to ask your doctor before using <TRADE NAME>.

Use in children

This product is not to be used by children under 8 years old.

Use in diabetics

<TRADE NAME> is suitable for diabetics. The powder does not contain any sugar.

Taking <TRADE NAME> with other products

Macrogol 4000 increases the osmotic pressure in the gut, and thus might modify the intestinal absorption of other products concomitantly administered.

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

Macrogol 4000 (10 g) without excipients

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.

<TRADE NAME> has a neutral taste and can be dissolved in water or in a drink of your choice (natural or sparkling mineral water, apple or orange juice, ice tea or hot water). Dissolve the contents of one sachet directly before intake in a glass of liquid (about 150 ml).

Adults and children aged 8 years and over:

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

1 – 2 sachets daily dissolved in liquid (equivalent to 10 - 20 g macrogol 4000), preferably taken as a single dose in the morning.

Children under 8 years should not use this product since other products are available that are better suited.

Within the dose recommendation the dose can be adjusted to your individual needs. It may range from one sachet every other day to two sachets per day. The right dose is the lowest dose to produce regular soft stools.

Please note:

<TRADE NAME> usually takes 24 - 72 hours to work. Clinical studies show that when administered regularly, the frequency of bowel movements tends to be one movement per day.

<For countries without any local requirement to limit the duration of use:>

<TRADE NAME> may be taken for a longer period of time. If your constipation persists, you should consult a doctor.

<For countries with local requirement to limit the duration of use:>

<TRADE NAME> may be taken for <limit for duration of use>. If your constipation persists, you should consult a doctor.

If you take more than the recommended dose

Excessive doses of <TRADE NAME> are likely to cause diarrhoea, abdominal pain, abdominal distension and vomiting which resolves when treatment is interrupted, or the dose is reduced.

Large fluid losses due to diarrhoea or vomiting may require correction of electrolyte imbalance. You should contact a doctor in these circumstances.

If you forget to take <TRADE NAME>

Do not take a double dose of <TRADE NAME> if you forgot to take the previous dose.

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4. Possible side effects

Side effects have generally been mild and transient.

Side effects:

Diarrhoea, abdominal pain, abdominal distension, nausea, vomiting, faecal incontinence and flatulence

Rarely anaphylactic shock, anaphylactic reaction, angioedema, urticaria, rash, hypersensitivity may occur.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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>

Keep medical devices out of the reach and sight of children.

Do not use <TRADE NAME> after the expiry date which is stated on the carton. The expiry date refers to the last date of that month.



Do not store <TRADE NAME> above 25°C.

6. Further information

The active principle in <TRADE NAME> is macrogol 4000.

1 sachet contains 10 g of macrogol as powder for oral solution (no excipients).



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Date of information: July 2025