

Macrogol 4000 (4 g) without excipients

Sachet

MACROGOL 4000 POWDER JUNIOR

Macrogol 4000 (4 g) powder for oral solution
in sachets, for children from 6 months to 12 years

For the symptomatic treatment of constipation



Expiry date:



Batch number:



Do not store above 25 °C!



Please follow instructions for use!

Macrogol 4000 (4 g) without excipients

**Manufacturer:**

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



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



Medical Device

Composition:

1 sachet with 4 g of powder contains:
Macrogol 4000 (polyethylene glycol): 4 g

The recommended initial dose is:

Age	Daily dose
6 months to 1 year	1 sachet
1 to 4 years	1 – 2 sachets
4 to 8 years	2 – 4 sachets
8 to 12 years	3 – 8 sachets

For further information regarding dosing please refer to the instructions for use.

Mode of administration:

The powder is dissolved in water and then drunk. At least 50 ml of water per sachet should be used for dissolution.

The solution may be given to the child over the course of the day. It may be stored in the refrigerator (2 °C to 8 °C) for not more than 24 hours. For further information regarding the preparation of the solution please refer to the instructions for use.

Keep out of the reach and sight of children!

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Carton box

MACROGOL 4000 POWDER JUNIOR

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in sachets, for children from 6 months to 12 years

6 sachets, each containing 4 g of powder for oral solution, sample not for sale

30 sachets, each containing 4 g of powder for oral solution

3 x 30 sachets, each containing 4 g of powder for oral solution

Composition:

1 sachet with 4 g of powder contains 4 g of macrogol 4000.

For the symptomatic treatment of constipation



batch number:



Expiry date:



25 °C

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UDI

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8 to 12 years	3 – 8 sachets

Mode of administration:

The powder is dissolved in water and then drunk. At least 50 ml of water per sachet should be used for dissolution.

The solution may be given to the child over the course of the day. It may be stored in the refrigerator (2 °C to 8 °C) for not more than 24 hours.

For further information regarding the dosage, mode of administration and the duration of the therapy please refer to the instructions for use.

Keep out of the reach and sight of children!

- Suitable for diabetics: The powder does not contain any sugar.
- Suitable for patients on a low sodium diet.
- Gluten-free

Macrogol 4000 (4 g) without excipients

Instructions for use

MACROGOL 4000 POWDER JUNIOR

Macrogol 4000 (4 g) powder for oral solution
in sachets, for children from 6 months to 12 years

MACROGOL 4000 POWDER JUNIOR is a medical device for the symptomatic treatment of constipation in children from 6 months to 12 years.



Please read these instructions for use carefully because they contain important information you have to consider before your child starts taking *MACROGOL 4000 POWDER JUNIOR*. You should always present your child to a paediatrician before using this product to have the cause of the constipation examined.

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

In this leaflet:

1. What *MACROGOL 4000 POWDER JUNIOR* is and what it is used for
2. What you need to know before taking *MACROGOL 4000 POWDER JUNIOR*
3. How to take *MACROGOL 4000 POWDER JUNIOR*
4. Possible side effects
5. How to store *MACROGOL 4000 POWDER JUNIOR* and how long can you keep it?
6. Further information

1. What *MACROGOL 4000 POWDER JUNIOR* is and what it is used for

MACROGOL 4000 POWDER JUNIOR (medical device) is a laxative for the symptomatic treatment of constipation in children from 6 months to 12 years of age.

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

2. What you need to know before taking *MACROGOL 4000 POWDER JUNIOR*

You should present your child to a paediatrician before giving *MACROGOL 4000 POWDER JUNIOR*.

Do not take *MACROGOL 4000 POWDER JUNIOR* if your child:

- is hypersensitive (allergic) to macrogol
- has stomach pain without knowing the cause
- has a bowel condition called “ileus” or a suspected blocked bowel (intestinal obstruction)
- has a hole (perforation) in his/her bowel wall or there is a danger of a perforation

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- has an inflammation of the bowel (small or large intestine), such as Crohn's disease or ulcerative colitis, or toxic megacolon

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, *MACROGOL 4000 POWDER JUNIOR* 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. patients with impaired hepatic or renal function or patients taking diuretics) and electrolyte control should be considered.

If you notice any of the above signs or symptoms, you should consult a physician or paediatrician immediately.

Use in diabetics

MACROGOL 4000 POWDER JUNIOR is suitable for diabetics. The powder does not contain any sugar.

Taking *MACROGOL 4000 POWDER JUNIOR* with other products

MACROGOL 4000 POWDER JUNIOR increases the osmotic pressure in the gut and thus might modify the intestinal absorption of medicinal products concomitantly administered.

If you need to thicken fluids in order for your child to swallow them safely, *MACROGOL 4000 POWDER JUNIOR* may counteract the effect of the thickener.

3. How to take *MACROGOL 4000 POWDER JUNIOR*

Always administer this medical device to your child exactly as advised by your doctor or pharmacist. Ask your doctor or pharmacist if you are not sure.

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Dosing:

It is recommended to start the treatment with a dose of 0.4 g of macrogol per kg of body weight. This is equivalent to 1 sachet MACROGOL 4000 POWDER JUNIOR per 10 kg of body weight. The following table serves as an orientation for the **initial dose**.

Age	Daily dose
6 months to 1 year	1 sachet (4 g)
1 to 4 years	1 to 2 sachets (4 to 8 g)
4 to 8 years	2 to 4 sachets (8 to 16 g)
8 to 12 years	3 to 8 sachets (12 to 32 g)

The therapy should be continued with the daily dose being adjusted to the individual need. The dose should be increased or decreased so that the child has a regular soft stool.

If the stool of your child becomes very soft or your child gets diarrhoea, you should lower the dose. In case your child takes more than one sachet of *MACROGOL 4000 POWDER JUNIOR* per day, the number of sachets may be reduced. In case your child takes only one sachet per day, the amount of solution that your child takes may be reduced.

If, after three days of treatment with the initial dose (see table), your child does not have a regular soft stool, the dose may be increased. Please consult your paediatrician before increasing the dose. The maximum daily dose is 1 g of macrogol per kg of body weight.

To find out the right dose for your child, it will be helpful to record the frequency and consistency of the stool in a stool diary. If you do so, you should always take it when you have a doctor's appointment so that your doctor can adjust the dose of *MACROGOL 4000 POWDER JUNIOR* accordingly.

Taking this medical device:

Dissolve the contents of one sachet in a glass of water and let your child drink it. Instead of water other liquids (e.g. fruit juices) may be used to dissolve the powder. A volume of at least 50 ml of liquid should be used for dissolution per sachet. Stir until the powder is dissolved completely and let your child drink the solution.

It is not necessary to drink the prepared solution at once. The solution may be administered in portions over the course of the day.

The solution may be stored in the refrigerator (2 °C to 8 °C) for not more than 24 hours.

Please note:

MACROGOL 4000 POWDER JUNIOR works gradually within 24 to 48 hours.

Duration of treatment:

MACROGOL 4000 POWDER JUNIOR may be taken for a longer period of time. The treatment of constipation with a laxative should be supportive in conjunction with a healthy life style and nutrition.

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If your child has taken more than the recommended dose

Excessive doses of *MACROGOL 4000 POWDER JUNIOR* are likely to cause side effects such as diarrhoea, abdominal pain, abdominal distension, feeling sick 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 your paediatrician in these circumstances.

If you forget to take *MACROGOL 4000 POWDER JUNIOR*

Do not give the double dose of *MACROGOL 4000 POWDER JUNIOR* to your child to make up the forgotten one.

4. Possible side effects

MACROGOL 4000 POWDER JUNIOR can cause side effects, although not everybody gets them. The following side effects may occur: feeling bloated, flatulence, stomach rumble, abdominal pain, digestive disorders (dyspepsia), anal discomfort, feeling sick, vomiting, diarrhoea. In rare cases hypersensitivity reactions (rash, itching, swelling of the face or more serious (anaphylactic) reactions with early symptoms such as restlessness, difficulty in breathing, swallowing and speaking or dizziness) may occur. In case of hypersensitivity reactions the treatment must be terminated.

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 *MACROGOL 4000 POWDER JUNIOR* and how long can you keep it?

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



Do not use *MACROGOL 4000 POWDER JUNIOR* after the expiry date which is stated on the sachets. The expiry date refers to the last day of that month. Opened or damaged sachets must not be used.



Do not store above 25°C.

The prepared solution may be stored in the refrigerator (2 °C to 8 °C) for not more than 24 hours.

6. Further information

What *MACROGOL 4000 POWDER JUNIOR* contains:

1 sachet contains 4 g Macrogol (PEG) 4000. *MACROGOL 4000 POWDER JUNIOR* does not contain any other substances.

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Suitable for patients on a low sodium diet.

Gluten-free

Date of information: September 2025

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Dear parents:

Your child is suffering from constipation. That probably comes along with stomach pain. Your child may as well complain about pain during defecation. Your paediatrician or pharmacist prescribed or recommended *MACROGOL 4000 POWDER JUNIOR* and gave you further advice that you should follow exactly.

What is the cause of constipation?

Constipation is not a sickness by itself, but a reaction to certain circumstances. The most probable causes may be an unbalanced diet (food low in fibre, consumption of too much food that causes constipation, such as chocolate), not drinking enough fluid and lack of physical exercise. Certain situations may make children refrain from going to the toilet, which, as a consequence, may lead to constipation. These situations may be:

- Change in the daily routine or the environment (e.g. trips)
- Uncertainty becoming clean
- Mental burden or new drastic experiences (e.g. birth of a sibling)
- Painful or unpleasant experience during defecation, e.g. fissures of the skin at the anus. These are typical triggers for children to sometimes refrain from defecation. This leads to harder stool which causes more pain the next time. It is a vicious circle!

Furthermore, there are medications and rare diseases that may cause constipation in children. You should definitely talk to your paediatrician about it.

How many times should a child have a bowel movement?

The “normal” frequency depends on many factors. It depends on the degree of physical exercise, the alimentation and the age that have an influence on the frequency. Infants being breastfed may, for example, have a bowel movement eight times a day or only once every two weeks, both may be fine. For toddlers and school children a stool frequency from three times a day to three times a week is fine. It is important that the child does not have any discomfort during defecation.

How can the constipation of my child be cured?

The aim of the therapy is a regular, complete and pain free defecation. Often enemas or solutions to drink containing an active substance are used at the beginning of the therapy so that jammed solid masses of stool come out. Then the treatment is continued with a stool softening medication. In most cases it takes several months to normalise the volume of the intestine which was previously enlarged by the accumulation of solid stool. For children from 6 months on *MACROGOL 4000 POWDER JUNIOR* can be used. It contains the active substance macrogol that is not resorbed from the intestine. It remains, together with the stool, in the intestine and retains water, which softens the stool. That way, defecation is facilitated. Any pain the child may have had before during defecation eases off.

When should I consult a paediatrician when my child is suffering from constipation?

Constipation is not an immediately dangerous condition. But pain and the associated behavioural problems affect the child. Constipation should therefore be diagnosed and treated as early as possible to avoid problems that come along with it.

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See your paediatrician if

- your child does not have any defecation for more than three days or portions of stool are very small and the child complains about pain.
- there is blood in the stool.
- stool comes off unnoticed from a child that is normally “clean”.
- your child, in addition, has a fever, feels sick, vomits or has a strong stomach ache.

How can I give my child support during the therapy?

In case the constipation occurs repeatedly, your paediatrician should rule out any organic disorders. He will advise you concerning additional measures.

You can do a few things yourself:

- It is important to let your child drink enough. That makes the stool softer and easier to glide.
- Take care that your child gets enough food that is rich in fibre, such as wholemeal products, fruits and vegetable.
- Reduce the amount of food that leads to constipation, e.g. chocolate.
- Enough physical activity in the form of fun and action help your child to avoid constipation.
- Take care of the bottom and the area of the anus of your child and treat small, painful fissures.
- With children aged 2 to 3 years a toilet training may be helpful. Let your child sit on the toilet or on the pot for about 5 to 10 minutes after each main meal. That way the defecation reflex is trained (take care that there is a support for the feet).
- Avoid making your child feel guilty. That may intensify the constipation problem.

Get well soon wishes (*Distributor*).