

Macrogol 3350 + electrolytes, (orange + lemon-lime)

Sachet

Macrogol 3350 + electrolytes laxative

For treatment of chronic constipation

Powder for oral solution



Expiry date:



Batch number:



Do not store above 25 °C!



Please read 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



Medical Device

Macrogol 3350 + electrolytes, (orange + lemon-lime)

Composition:

1 sachet with 13.81 g of powder contains:

13.125 g of macrogol (PEG) 3350,

sodium chloride, sodium hydrogen carbonate, potassium chloride, lemon-lime flavour (contains sorbitol), orange flavour, saccharin sodium, colloidal silica

How to take:

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

Adults, adolescents from 12 years on and elderly patients:

Unless otherwise prescribed by the doctor, in the event of chronic constipation, dissolve and drink the contents of one sachet 1-3 times a day. If there is no improvement after 2 weeks, please see your doctor.

The reconstituted solution, ready to use, can be covered and stored in the refrigerator (2°C - 8°C) and should be used within twenty-four hours.

Keep out of reach of children!

Macrogol 3350 + electrolytes, (orange + lemon-lime)

Carton box

Macrogol 3350 + electrolytes laxative

x sachets with 13.81 g of powder each, powder for oral solution.

Composition:

1 sachet of 13.81 g powder contains:

13.125 g of macrogol (PEG) 3350,

sodium chloride, sodium hydrogen carbonate, potassium chloride, lemon-lime flavour (contains sorbitol), orange flavour, saccharin sodium, colloidal silica

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

Adults, adolescents from 12 years on and elderly patients:

Unless otherwise prescribed by the doctor, in the event of chronic constipation, dissolve and drink the contents of one sachet 1-3 times a day. *Macrogol + electrolytes laxative* is suited for long term use. For the treatment of constipation a laxative should be used in support of a healthy lifestyle and diet. If there is no improvement, please see your doctor.

The reconstituted solution, ready to use, can be covered and stored in the refrigerator (2°C - 8°C) and should be used within twenty-four hours.



Batch number:



Expiry date:



Do not store above 25 °C!



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Keep out of reach of children!



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Instructions for use

Macrogol 3350 + electrolytes laxative

For treatment of chronic constipation

Powder for oral solution



Please read the entire instructions for use carefully, because it contains important information for you.

This medical device is available without prescription. However, to achieve the best possible treatment success, *Macrogol 3350 + electrolytes laxative* must be taken as directed.

- Keep the instructions for use. You might want to read it again.
- Ask your pharmacist, if you need further information or any advice.
- If your symptoms worsen or if there is no improvement after 14 days, you must definitely see a doctor.
- If any of the side effects listed, affects you significantly or if you notice any side effects that are not listed in these instructions for use, please inform your doctor or pharmacist.

These instructions for use contain:

1. What *Macrogol 3350 + electrolytes laxative* is and what it is used for
2. What you need to know before you take *Macrogol 3350 + electrolytes laxative*
3. How to take *Macrogol 3350 + electrolytes laxative*
4. Possible side effects
5. How to store *Macrogol 3350 + electrolytes laxative* and how long it can be used
6. Further information

1. What Macrogol 3350 + electrolytes laxative is and what it is used for

Macrogol 3350 + electrolytes laxative (medical device) is a laxative used for the treatment of chronic constipation. It is not recommended for children below 12 years of age. Macrogol 3350 makes your faeces softer, triggers the natural movement of the bowel and therewith facilitates defecation. In most cases, normal bowel movement and stool frequency will return within 24-48 hours. It is effective locally in the intestine and is not taken up by the body.

2. What you need to know before you take Macrogol 3350 + electrolytes laxative

Do not take *Macrogol 3350 + electrolytes laxative* if you

- are hypersensitive (allergic) to macrogol 3350, sodium chloride, sodium hydrogen carbonate, potassium chloride, or any of the other ingredients in *Macrogol 3350 + electrolytes laxative*
- have a perforated gut (bowel) wall,

Macrogol 3350 + electrolytes, (orange + lemon-lime)

- have a blockage in your intestine (intestinal obstruction, ileus),
- have a severe inflammatory bowel disease, such as ulcerative colitis, Crohn's disease or toxic megacolon,

If any of these applies to you, please talk to your doctor or pharmacist.

Taking medicines

Some medicines, e.g. anti-epileptics, may not work as effectively when concomitantly used with *Macrogol 3350 + electrolytes laxative*.

Please tell your doctor or pharmacist if you are taking, or have recently taken any medicines, including medicines obtained without a prescription.

Taking together with food or drinks

Macrogol 3350 + electrolytes laxative can be taken at any time with or without food or drink.

If you need to thicken fluids in order to swallow them safely, *Macrogol 3350 + electrolytes laxative* may counteract the effect of the thickener.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, talk to your doctor before taking *Macrogol 3350 + electrolytes laxative*.

Driving and using machines

Macrogol 3350 + electrolytes laxative has no effect on the ability to drive or use machinery.

Important information about some of the ingredients of *Macrogol 3350 + electrolytes laxative*

Macrogol 3350 + electrolytes laxative contains 0.63 mmol (25 mg) of potassium per sachet. This should be taken into consideration if you take more than one sachet daily and you are suffering from a reduced kidney function, or if you are on a controlled potassium diet.

Macrogol 3350 + electrolytes laxative contains 8.1 mmol (187 mg) of sodium per sachet. This should be taken into consideration if you are on a controlled sodium diet.

The lemon-lime-flavour in *Macrogol 3350 + electrolytes laxative* contains sorbitol. Please consult your doctor before taking this medical device if you know that you are intolerant to some sugars.

3. How to take *Macrogol 3350 + electrolytes laxative*

Adults, adolescents from 12 years on and elderly patients

The usual dose is one sachet taken one to three times daily.

How to prepare

Open the sachet and pour the contents into a glass. Add about 125 ml (1/8 litre) of water. Stir well until the powder has dissolved and then drink the solution.

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Duration of treatment

Macrogol 3350 + electrolytes laxative can be used over a longer period of time. For the treatment of constipation a laxative should be used in support of a healthy lifestyle and diet.

If you take more *Macrogol 3350 + electrolytes laxative* than you should

This can cause severe pain and swelling in your abdomen (stomach) or vomiting (sickness) or diarrhoea. If this happens, contact your doctor or pharmacist.

If you forget to take *Macrogol 3350 + electrolytes laxative*:

If you forget to take a dose of *Macrogol 3350 + electrolytes laxative*, take the dose as soon as you remember and then continue as before. Do not take a double dose to make up for a forgotten one.

If you stop taking *Macrogol 3350 + electrolytes laxative*:

To get the most benefit from *Macrogol 3350 + electrolytes laxative*, always finish the course of treatment according to the directions in this package leaflet. This will make sure that your constipation is cleared, otherwise the symptoms you are suffering from may persist.

You must contact a doctor if your symptoms worsen or do not improve within 14 days.

If you have any questions how to use this medical device, ask your doctor or pharmacist.

4. Possible side effects

If you experience any of the following side effects, stop taking *Macrogol 3350 + electrolytes laxative* and see your doctor immediately:

- Signs of an allergy, such as a rash, itching, shortness of breath or difficulty in breathing
- Signs of a change in your body's fluid or electrolyte (salt) imbalance, such as swelling (mainly in the ankles), feeling weak or tired or becoming thirstier with headache

The following side effects are also possible:

- Abdominal (stomach) pain
- Mild diarrhoea (especially when starting to take this product). This usually gets better when reducing the dosage.
- Nausea (feeling sick)
- Vomiting
- Swelling of your abdomen (feeling bloated)
- Stomach rumbling
- Flatulence (wind)
- Soreness of the anus (bottom)

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*.

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5. How to store *Macrogol 3350 + electrolytes laxative* and how long it can be used

Keep out of the reach and sight of children.

Do not use *Macrogol 3350 + electrolytes laxative* after the expiry date which is stated on the carton and sachet. The expiry date refers to the last day of that month and is marked with the symbol:



Do not store above 25°C!

Do not use *Macrogol 3350 + electrolytes laxative* if you notice that any of the sachets is damaged.

The reconstituted solution, ready to use, can be covered and stored in the refrigerator (2°C - 8°C) and should be used within twenty-four hours. After twenty-four hours, any unused solution should be discarded.

Unused *Macrogol 3350 + electrolytes laxative* sachets should not be disposed of in the waste water or household waste. Ask your pharmacist how to dispose of unused sachets when you no longer need them. This measure helps to protect the environment.

6. Further information

What *Macrogol 3350 + electrolytes laxative* contains:

Each sachet contains:

13.125 g macrogol (PEG) 3350,
sodium chloride, sodium hydrogen carbonate, potassium chloride, colloidal silica, saccharin sodium, orange flavour (orange flavour contains: flavouring substances, maltodextrin, gum arabic and alpha-tocopherol) and lemon-lime flavour (lemon-lime flavour contains: flavouring substances and extracts, maltodextrin, mannitol, gluconolactone, sorbitol, acacia gum and colloidal silica).

What *Macrogol 3350 + electrolytes laxative* looks like and contents of the pack

Macrogol 3350 + electrolytes laxative is a white powder.

Each sachet contains 13.81 g of powder and is packed in cartons containing *x* sachets.



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