Package leaflet: Information for the patient

Macrogol en elektrolyten naturel Sandoz® 13,7 g, poeder voor drank

macrogol 3350 / sodium chloride / sodium hydrogen carbonate / potassium chloride

[For medicines available only on prescription:] [To be completed nationally]
Read all of this leaflet carefully before you start taking this medicine because it contains important information for you
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

[For medicines available without a prescription:] [To be completed nationally]
Read all of this leaflet carefully before you start taking this medicine because it contains important information for you
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days for chronic constipation, or after 3 days for faecal impaction. [For faecal impaction indication only]

What is in this leaflet

1. What [Nationally completed name] is and what it is used for

[Nationally completed name] is a laxative used for the treatment of constipation (especially if constipation lasts a long time) in adults, adolescents and elderly. It is not recommended for children below 12 years of age.

[For faecal impaction indication only:]

It is also used to treat a build up of hard faeces in your bowel which may be a result of long-term constipation (this is known as faecal impaction).

Macrogol 3350 makes your faeces softer and easier to pass, giving you relief from constipation. The electrolytes (salts) help to maintain your body's normal levels of sodium, potassium and water while you are beeing treated for constipation.

2. What you need to know before you take [Nationally completed name]

Do not take [Nationally completed name]

- if you are allergic to macrogol 3350, sodium chloride, sodium hydrogen carbonate, potassium chloride, or any of the other ingredients in this medicine (listed in section 6)
- if you have a perforated gut (bowel) wall
- if you have a blockage in your intestine (gut obstruction, ileus)
- if you have severe inflammatory bowel disease such as ulcerative colitis, Crohn's disease or toxic megacolon

Talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions

[For faecal impaction indication only:]

Before taking [Nationally completed name] to treat faecal impaction, you should have this condition confirmed by your doctor.

If you have heart condition and you take product for faecal impaction, follow the special instructions in section 3.

If you develop side effects such as swelling, shortness of breath, feeling tired, dehydration (symptoms include increasing thirst, dry mouth and weakness) or heart problems you should stop taking [Nationally completed name] and contact your doctor immediately.

If you experience sudden abdominal pain or rectal bleeding when taking [Nationally completed name] for bowel preparation, contact your doctor or seek medical advice immediately.

Children

Do not give this medicine to children below 12 years of age.

Other medicines and [Nationally completed name]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines, e.g. anti-epileptics, may not work as effectively during use with [Nationally completed name]. Therefore, other medicines should not be taken orally for one hour before and for one hour after taking this medicine.

If you need to thicken fluids in order to swallow them safely, [Nationally completed name] may counteract the effect of the thickener.

Pregnancy and breast-feeding

[Nationally completed name] can be taken during pregnancy and whilst breast-feeding. If you are pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

This medicine does not affect your ability to drive or use machines.

[Nationally completed name] contains sodium and potassium

This medicine contains 188 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 9.4% of the recommended maximum daily dietary intake of sodium for an adult.

The maximum recommended daily dose of this medicine when used for constipation contains 564 mg sodium (found in table salt). This is equivalent to 28.2 % of the adult recommended maximum daily dietary intake for sodium.

Talk to your doctor or pharmacist if you need three or more sachets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

[For faecal impaction indication only:]

The maximum recommended daily dose of this medicine when used for faecal impaction contains 1504 mg sodium (found in table salt). This is equivalent to 75.2 % of the adult recommended maximum daily dietary intake for sodium.

Talk to your doctor or pharmacist if you need three or more sachets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

This medicine contains 0.6 mmol (or 24.4 mg) potassium per sachet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

3. How to take [Nationally completed name]

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Constipation

A dose of [Nationally completed name] is 1 sachet dissolved in 125 ml (1/4 pint) of water. Take this 1-3 times a day according to the severity of your constipation.

Treatment with this medicine usually lasts for about 2 weeks. If you need to take this medicine for longer, please see your doctor. If your constipation is caused by an illness such as Parkinson's disease or multiple sclerosis (MS), or if you take medicines that cause constipation your doctor may recommend that you take this medicine for longer than 2 weeks. If you need to take this medicine for longer, please see your doctor. Usually for long term treatment the dose can be lowered to either 1 or 2 sachets a day.

[For faecal impaction indication only:]

Faecal impaction

Before you take this medicine for faecal impaction, it should be confirmed that you have this condition. A dose of 8 sachets a day of [Nationally completed name] is needed for the treatment of faecal impaction. Each sachet is dissolved in 125ml (1/4 pint) of water. The 8 sachets should be taken within 6 hours for up to 3 days if required. If you have a heart condition, do not take more than 2 sachets in any one hour.

How to mix

Open the sachet and pour the contents into a glass. Add about 125 ml or a quarter pint of water to the glass. Stir well until all the powder has dissolved and the solution is clear or slightly hazy, then drink it.

[For faecal impaction indication only:]

If you are being treated for faecal impaction, you can dissolve the contents of all eight sachets together in a large container (in one litre of water).

This medicine should be taken orally.

Children

Do not give this medicine to children below 12 years of age.

If you take more [Nationally completed name] **than you should**

This can cause severe pain and bloated stomach, vomiting (sickness) or diarrhoea. Excessive diarrhoea can lead to dehydration. If this occurs, stop taking this medicine and drink plenty of fluids. If you are worried contact your doctor or pharmacist.

If you forget to take [Nationally completed name]

Take the dose as soon as you remember to take it.

4. Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them.

If you experience any of the following side effects, stop taking [Nationally completed name] and see your doctor immediately:

- If you get signs of an allergy, such as a rash, itching, reddening of the skin, shortness of breath, difficulty in breathing, or swelling of the face, lips, tongue or throat.
- If you get signs of a change in your body's fluid or electrolyte levels (salts levels), such as swelling (mainly in the ankles), feeling weak, dehydration, increasingly tired or increased thirst with headache. These symptoms may be a sign that the potassium levels in your blood are higher or lower than normal.

Other side effects include:

- swollen hands, feet or ankles
- headaches
- indigestion, stomach ache or rumbles
- feel bloated, suffer from wind, feel sick or vomit
- soreness of the anus (bottom)
- diarrhoea (when starting to take this medicine)
- change in your body's fluid or electrolyte levels (low levels of sodium)

These side effects generally get better if you reduce the amount of [Nationally completed name] you take.

The frequencies of these side effects are not known (cannot be estimated from the available data).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Nationally completed name]

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and sachet after "EXP". The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Reconstituted [Nationally completed name] solution can be covered and stored in the refrigerator (2°C to 8°C), and should be used within twenty-four hours. After twenty-four hours, any unused solution should be discarded.

Do not use this medicine if you notice that any of the sachets is damaged.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [Nationally completed name] contains

The active substances are:

Each sachet contains:

macrogol 3350	13.125 g
sodium chloride	0.3507 g
sodium hydrogen carbonate	0.1785 g
potassium chloride	0.0466 g

The other ingredient is colloidal anhydrous silica

What [Nationally completed name] looks like and contents of the pack

[Nationally completed name] is a white crystalline powder.

The sachet is composed of paper, polyethylene and aluminium.

Each sachet contains 13.7 g of powder and is packed in cartons containing 2, 6, 8, 10, 20, 30, 50, 60 (2x30) and 100 (2x50) sachets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen
Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Nederland

Fabrikant
Klocke Pharma-Service GmbH
Strassburger Strasse 77,
77767 Appenweier
Duitsland

Salutas Pharma GmbH
Otto-von-Guericke Allee 1
39179 Barleben
Duitsland

Hermes Pharma GmbH
Schwimschulweg 1a
9400 Wolfsberg
Oostenrijk

In het register ingeschreven onder:
Macrogol en elektrolyten naturel Sandoz 13,7 g is in het register ingeschreven onder RVG 123358.

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Denemarken:	Gangiden neutral
Nederland:	Macrogol en elektrolyten naturel Sandoz 13,7 g, poeder voor drank
Zweden:	Laxiriva Neutral, pulver till oral lösning i dospåse

Deze bijsluiter is voor het laatst goedgekeurd in februari 2024.