Package leaflet: Information for the patient

TRANSISOFT 8.5 g powder for oral solution in sachet
Macrogol 3350

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 have 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.

What is in this leaflet

1. What TRANSISOFT 8.5 g is and what it is used for

How it works
It belongs to a group of medicines called osmotic laxatives.This medicine carries water to your stool, which loosens and increases stool volume, helping to overcome sluggish bowels. It is not absorbed into the bloodstream or broken down in the body.

What it is used for
This medicine is used for the treatment of chronic constipation in adults. It is not recommended for children below 17 years of age.

2. What you need to know before you take TRANSISOFT 8.5 g

Information on constipation treatment
The treatment of chronic constipation with any medicine should only be in addition to a healthy lifestyle and diet, for example:
- increase the proportion of vegetal source products in the diet (vegetables, bread, fruits),
- increase water and fruit juice intake,
- increase physical activity (sports, walking…),
- rehabilitation of defecation reflex.

Do not take TRANSISOFT 8.5 g
- If you are allergic (hypersensitive) to the active substance (macrogol = P.E.G. = polyethylene glycol).
- If you have severe inflammatory bowel disease (such as ulcerative colitis, Crohn's disease or toxic megacolon, associated with bowel narrowing).
- If you have a perforated gut wall or a risk of perforated gut wall.
- If you have a blockage in your intestine (gut obstruction, ileus) or symptomatic stenosis.
- If you have painful abdominal condition of unknown cause.

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your pharmacist or doctor before taking the medicine.

Warnings and precautions

- An allergic reaction may occur. The warnings signs of an allergic reaction and the actions to be taken are stated in section 4. Please read carefully this section.
- This medicine is sugar free so it can be used if you are diabetic or if you should follow a galactose-free diet.
- 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 TRANSISOFT 8.5 g and contact your doctor immediately.

As this medicine can sometimes cause diarrhoea, check with a doctor or pharmacist before taking this medicine if you:

- have impaired liver or kidney function,
- are taking diuretics (water tablets) or are elderly as you may be at risk of low sodium (salt) or potassium levels in the blood.

Other medicines and TRANSISOFT 8.5 g

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines e.g. anti-coagulants or anti-epileptics, may not work as effectively during use with TRANSISOFT 8.5 g.

If you need to thicken fluids in order to swallow them safely, TRANSISOFT 8.5 g may counteract the effect of the thickener.

Pregnancy and breast-feeding

This medicine can be taken during pregnancy and whilst breast-feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

This medicine has no effect on your ability to drive a car or to operate a machine.

3. How to take TRANSISOFT 8.5 g

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

How many sachets should you take

The recommended dose is 2 sachets per day.

When should you take the sachet(s)

This medicine should be taken as a single dose, preferably in the morning.

How to take your dose

Dissolve the contents of the sachets in a ½ glass of water (100 mL) immediately before use and drink the liquid.
The dissolved solution remains as clear as water.

How long it usually takes to work

This medicine usually takes 24 to 48 hours to work. However talk to a doctor if symptoms do not improve after 5 days of using TRANSISOFT 8.5 g.

If you take more TRANSISOFT 8.5 g than you should

- It may cause diarrhoea, which usually disappears when treatment is stopped or the dose reduced.
- If you suffer from severe diarrhoea or vomiting you should contact a doctor as soon as possible as you may require treatment to prevent loss of salts due to fluid loss.

If you forget to take TRANSISOFT 8.5 g
Do not take a double dose to make up for a forgotten sachet.

4. Possible side effects

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

Allergic reactions
- **The warning signs of an allergic reaction are**: difficulty in breathing, or swelling of the face, lips, tongue or throat, skin rash, itching and reddening of the skin.
- If you experience one of these side effects, **you should stop the treatment and consult a doctor immediately.**

Side effects in adults:
- **Very Common (may affect more than 1 in 10 people):** diarrhoea.
- **Common (may affect up to 1 in 10 people):** abdominal pain, swollen abdomen (abdominal distention), wind (flatulence), vomiting, feeling sick (nausea), abnormal liver function tests.
- **Uncommon (may affect up to 1 in 100 people):** low level of red blood cells, increased heartrate (tachycardia), hypothyroidism, fatigue, peripheral oedema, pain, intestinal abcess, viral gastroentiritis, high level of amylase in the blood, high level of CPK in the blood, high level of glucose in the blood, increased red blood cell sedimentation rate, appetite disorder, dehydration, low level of sugar in the blood (hypoglycaemia), local swelling, muscle twitching, dizziness, altered sense of taste (dysgueusia), migraine, inflammation of a nerve (neuritis), pelvic pain, sinus congestion, hiccups, acne, rash, urticaria, high blood pressure, allergic reactions, change in your body's fluid or electrolyte levels (low levels of sodium (hyponatreamia) and potassium (hypokalaemia) in blood) especially in elderly patients (over 65 years of age).

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 HPRA Pharmacovigilance Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store TRANSISOFT 8.5 g

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 the sachet. The expiry date refers to the last day of that month.

Reconstituted solution must be used immediately.

This medicine does not require any special storage conditions.

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 TRANSISOFT 8.5 g contains
The active substance is macrogol 3350 (Macrogol is also known as polyethylene glycol or PEG). Each sachet contains 8.5 grams of macrogol 3350.

What TRANSISOFT 8.5 g looks like and contents of the pack
This medicine is a white or almost white powder in a sachet for making up a solution.
It is available in packs of 14 or 28 sachets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Laboratoires MAYOLY SPINDLER
6, avenue de l'Europe – B.P. 51
78401 CHATOU CEDEX - France

Manufacturer
Recipharm Höganäs AB
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SE-263 35 Höganäs
SWEDEN

This medicinal product is authorised in the Member States of the European Economic Area and d in the United Kingdom (Northern Ireland) under the following names:

Belgium, Germany, Italy, Ireland, United-Kingdom (Northern Ireland) : TRANSISOFT®
France : Macrogol 3350 MAYOLY-SPINDLER

This leaflet was last revised in 11/2021

Detailed information on this medicine is available on the website of:

Ireland: HPRA
Website: www.hpra.ie