

Package leaflet: information for the user

Endofalk® Powder for oral solution

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 doctor or 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.

What is in this leaflet:

1. What Endofalk is and what it is used for
2. What you need to know before you take Endofalk
3. How to take Endofalk
4. Possible side effects
5. How to store Endofalk
6. Contents of the pack and other information

1. What Endofalk is and what it is used for

Endofalk Powder for oral solution contains a mixture of various salts and macrogol (a stool softener) and is used as a bowel cleansing agent. For further details on the ingredients please see Section 6.

You are taking Endofalk to make your bowels clean so that they are ready for examination (colonoscopy).

Endofalk works by emptying the contents of your bowels, so you should expect to have watery bowel movements.

2. What you need to know before you take Endofalk

Do NOT take Endofalk if you have:

- An allergy to macrogol 3350, sodium chloride, sodium hydrogen carbonate, potassium chloride or any of the other ingredients of this medicine (listed in section 6).
- paralysis or suspected paralysis of your gut (ileus)
- a blockage or suspected blockage in your intestine
- a perforated gut wall or danger of a perforated gut wall
- severe inflammatory bowel disease such as severely active ulcerative colitis, Crohn's disease or an enlarged colon (toxic megacolon)
- a disorder of stomach emptying
- general weakness and / or are feeling faint
- a reduced level of consciousness
- a problem swallowing
- a tendency to choke or breathe in food and / or fluids.

Warnings and precautions

Talk to your doctor before taking Endofalk if you have:

- heart failure
- heart rhythm disturbance (cardiac arrhythmia)
- kidney failure
- liver disease
- chronic inflammatory bowel disease
- inflammation of the oesophagus because of reflux of gastric acid
- severe dehydration

If you are **elderly** or debilitated, your salt (electrolyte) and water levels will be carefully monitored.

If you experience sudden abdominal pain or rectal bleeding when taking Endofalk for bowel preparation, contact your doctor or seek medical advice immediately.

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 Endofalk and contact your doctor immediately.

Other medicines and Endofalk

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 Endofalk. Speak to your doctor if you need to take any vital medications; an alternative may be given.

Endofalk with food and drink

Do **not** add any other solutions or additives (especially sugar or flavouring substances) to Endofalk Powder except for water. This could lead to a change in the strength of the solution or in the salt balance. In addition, when the solution is broken down by the intestinal bacteria, explosive mixtures of gases can develop in the intestine.

Do **not** drink anything other than the Endofalk solution and water.

Do **not** eat any food from 2 – 3 hours before taking Endofalk until after your examination.

Pregnancy and 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.

There is no experience with the use of Endofalk during pregnancy.

It is not known if the active substance macrogol is excreted in milk. This active substance is taken up from your gastrointestinal tract only to a very minor extent.

If you are pregnant or breastfeeding you can use Endofalk only, if your doctor tells you to.

Driving and using machines

Endofalk does not affect your ability to drive and use machines.

Endofalk contains sodium and potassium.

This medicine contains 32.5 mmol (or 747 mg) of sodium (main component of cooking/table salt) per sachet.

This is equivalent to 37.4% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 2.5 mmol (or 97.5 mg) potassium per sachet. This should be taken into consideration if you have reduced kidney function or if you are on a controlled potassium diet.

In these cases, please contact your doctor or pharmacist.

3. How to take Endofalk

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

Remember you need to be close to toilet facilities whilst you are taking Endofalk.

Preparation of the solution:

- Empty the contents of 2 sachets of Endofalk in half a litre of water (lukewarm tap water or cooled boiled water). Then add another half-litre of water.
- Do not add any other solutions or additives (especially not sugar or flavouring substances) to the Endofalk solution except for water.
- Stir well until all the solution is clear or slightly hazy.
- The prepared solution can then be put into a refrigerator to cool. The solution may be more pleasant to drink when it is cool.

The ready-to-drink solution can be stored for not more than 3 hours at room temperature (below 25 °C) or for a maximum of 48 hours in the refrigerator (2 °C – 8 °C).

Dosage for adults (over 18 years of age)

The usual dose is 3 litres to a maximum of 4 litres of Endofalk solution. To make up 3 litres of solution you will need 6 sachets dissolved in 3 litres of water, and to prepare 4 litres of solution you will need 8 sachets dissolved in 4 litres of water (see Preparation of the solution).

Drink 200ml – 300ml of the solution (about one large glass full) every 10 minutes until bowel movements are clear liquid only.

Use in children

Endofalk should not be given to children.

When to take Endofalk solution:

You should have been given instructions about when to take Endofalk by your doctor or nurse.

Your treatment with Endofalk solution must be completed before your examination.

- If you have an **afternoon appointment** for the examination, take the solution over a period of about 4 hours in the morning of this day. Alternatively, take part of it on the evening before and the remainder on the morning of the examination day.
- If you have a **morning appointment** for the examination, take the entire solution on the evening before the examination day over a period of about 4 hours.

Important:

Do **not** eat any food from 2 – 3 hours before administration of Endofalk until after the examination.

Do **not** drink anything other than the Endofalk solution and water.

If you feel that the effect of Endofalk is too strong or too weak, talk to your doctor.

If you take more Endofalk than you should

If you take more than 3 to 4 litres, corresponding to 6 to 8 sachets, you may develop severe diarrhoea. If this happens, contact your doctor and drink plenty of fluid. Stop taking Endofalk until it clears.

If you forget to take Endofalk

If you drink a lot less than the recommended amount of Endofalk solution, your bowel may not be completely emptied. Therefore, it may not be possible to carry out the examination as planned. To avoid this please follow the dosage recommendations given by your doctor and the instructions in this leaflet carefully.

If you forget to drink the solution, take the next dose as soon as you remember to take it. Continue as recommended until you have drunk all the required quantity.

If you stop taking Endofalk

If you stop taking Endofalk solution too soon, your bowel may not be completely emptied. Therefore, it may not be possible to carry out the examination as planned.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking Endofalk and see your doctor **immediately** if you experience any of the following side effects:

- Skin rash, itching, dizziness or difficulty in breathing (signs of an allergic reaction) or serious allergic reaction (anaphylactic shock)
- Tiredness, feeling weak, very thirsty with headache, swelling of the ankles (signs of changes in your body's fluid or electrolyte levels)
- Severe vomiting as this could lead to bleeding due to tearing of the gullet (Mallory-Weiss syndrome)

The following side effects are largely due to drinking relatively large amounts of fluid within a short time. If they occur, slow down drinking Endofalk solution temporarily or stop drinking until symptoms disappear.

Very common may affect more than 1 in 10 people

:

- Feeling sick
- A feeling of fullness
- Suffering from wind

Common may affect up to 1 in 10 people:

- Vomiting
- Stomach cramps
- Irritation of the anus

Not known: frequency cannot be estimated from the available data

- Nettle rash, nasal discharge, runny nose or acute inflammation of the skin
- Neurological symptoms that can range from mild disorientation to generalised seizures (resulting from a disturbance of salts (electrolytes) in the blood)

- Signs of a severe allergic reaction (anaphylactic shock)
- Irregular or too rapid heartbeat
- Accumulation of fluid in the lungs
- Generally feeling unwell and sleeping problems
- Vomiting followed by bleeding due to tearing of the gullet (Mallory-Weiss syndrome)
- Dehydration, change in your body's fluid and electrolyte levels (low levels of calcium, low levels of potassium, low levels of sodium),

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 Endofalk

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

Sachets: This medicine does not require any special storage conditions. The ready-to-drink solution can be stored for no more than 3 hours at room temperature (below 25 °C) or for a maximum of 48 hours in the refrigerator (2 °C – 8 °C).

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Endofalk contains:

Each sachet of Endofalk contains the following **active** substances:

- | | |
|-----------------------------|---------|
| • Macrogol 3350 | 52.500g |
| • Sodium chloride | 1.400g |
| • Sodium hydrogen carbonate | 0.715g |
| • Potassium chloride | 0.185g |

The **other** ingredients are saccharin sodium, orange and passion fruit flavour, and colloidal anhydrous silica (*see end of Section 2 for further information about sodium and potassium*)

What Endofalk looks like and contents of the pack:

Endofalk is a white powder for oral solution packed in sachets.

Endofalk is available in packs of 6 or 72 sachets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Dr Falk Pharma GmbH
Leinenweberstrasse 5
79108 Freiburg
Germany
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This medicinal product is authorised in the Member States of the EEA under the following name:

Germany: Colosol; Austria, Belgium, Denmark, Ireland, Luxembourg, Norway, Portugal, Sweden and United Kingdom: Endofalk

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