

PACKAGE LEAFLET: INFORMATION FOR THE USER

ELAXIGOL

13.7g sachet, 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, pharmacist or nurse has told you.

- *Keep this leaflet. You may need to read it again.*
- *If you have further questions, ask your doctor, pharmacist or nurse.*
- *This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours. • If you get any of the side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.*

What is in this leaflet:

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

1. What Elaxigol is and what it is used for

The name of this medicine is Elaxigol 13.7g sachet, powder for oral solution. It is a laxative for the treatment of constipation in adults, adolescents and the elderly. This product is not recommended for children below 12 years of age.

It helps you to have a comfortable bowel movement even if you have been constipated for a long time. Elaxigol 13.7g sachet also works in very bad constipation called faecal impaction.

2. What you need to know before you take Elaxigol

Do not take Elaxigol if your doctor has told you that you have:

- a blockage in your intestine (gut obstruction, ileus)
- a perforated gut wall.
- severe inflammatory bowel disease like ulcerative colitis, Crohn's disease or toxic megacolon
- an allergy to the active substances or any of the other ingredients of Elaxigol (listed in section 6).

Warnings and precautions

When taking Elaxigol 13.7g sachet, you should continue to take plenty of fluids. The fluid content of Elaxigol 13.7g sachet should not replace your regular liquid intake.

Talk to your doctor or pharmacist before taking Elaxigol.

Heart conditions

Follow the special instructions in section 3 if you are taking Elaxigol for faecal impaction.

Other medicines and Elaxigol

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

Some medicines, e.g. anti-epileptics, may not work as effectively during use with Elaxigol.

Pregnancy and breast-feeding.

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

Driving and using machines

Elaxigol has no effect on the ability to drive or use machines.

Elaxigol contains Sodium

Talk to your doctor or pharmacist if you need 3 or more sachets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet. Elaxigol contains 186.87 mg sodium (main component of cooking/table salt) per sachet. This is equivalent to 9.3% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Elaxigol

This medicine can be given at any time with or without food.

Dissolve the content of each sachet in 125 ml (1/4 pint) of water and drink.

Constipation:

A dose of Elaxigol 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.

Faecal Impaction

Before you take Elaxigol for faecal impaction, it should be confirmed that you have this condition.

A dose of 8 sachets a day of Elaxigol is needed for the treatment of faecal impaction. Each sachet dissolved in 125 ml (1/4 pint) of water. The 8 sachets should be taken within 6 hours period 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 125ml or 1/4 pint of water to the glass. Stir well until all the powder has dissolved and the Elaxigol solution is clear or slightly hazy, then drink it. If you are taking Elaxigol for faecal impaction it may be easier to dissolve 8 sachets in 1 litre of water.

Duration of treatment:

Constipation:

Treatment with Elaxigol usually lasts up to 2 weeks. If you need to take Elaxigol 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 Elaxigol for longer than 2 weeks. If you need to take Elaxigol for longer, please see your doctor.

Usually for long term treatment that dose can be lowered to either 1 or 2 sachets a day.

Faecal impaction:

Treatment with Elaxigol can be for up to 3 days.

If you take more Elaxigol than you should

You may develop excessive diarrhoea, which may lead to dehydration. If this occurs, stop taking **Elaxigol** and drink plenty of fluids. If you are worried contact your doctor or pharmacist.

If you forget to take Elaxigol

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

4. Possible side effects

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

Tell your doctor immediately and stop taking Elaxigol if you:

- Get a serious allergic reaction which causes difficulty in breathing, or swelling of the face, lips, tongue or throat.

Other side effects include:

Allergic reactions which may cause a skin rash, itching, reddening of the skin or a nettle rash, swollen hands, feet or ankles, headaches and high and low levels of potassium in the blood.

Sometimes you may have indigestion, stomach ache or rumbles. You may also feel bloated, suffer from wind, feel sick or vomit, may also experience soreness of the anus (bottom) and may have mild diarrhoea when starting to take Elaxigol. These side effects generally get better if you reduce the amount of Elaxigol you take.

If any of the above are troublesome or last more than a few days, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Elaxigol

Keep out of the sight and reach of children.

Do not use Elaxigol 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.

Sachet: This medicinal product does not require any special storage conditions.

Once you have made up Elaxigol in water, if you cannot drink it straight away keep it covered and in the refrigerator (2 – 8°C). Throw away any solution not used within a 24 hour period.

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 Elaxigol contains

- The active substances are
 - Macrogol 3350 (13.125g)
 - Sodium chloride (0.3507g)
 - Sodium hydrogen carbonate (0.1785g)
 - Potassium chloride (0.0466g).
- Elaxigol also contains lemon flavour and acesulfame potassium (E950) as a sweetener. The lemon flavour contains the following ingredients: acacia gum (E414) and flavouring containing lemon/lime oil.

When it is made into a drink with 125 millilitres of water, each sachet gives the equivalent of:

Sodium	65 millimoles/litre
Chloride	53 millimoles/litre
Potassium	5.4 millimoles/litre
Hydrogen carbonate	17 millimoles/litre

What Elaxigol looks like and contents of the pack

Elaxigol is a white powder packed in sachets. Following reconstitution the product is an oral solution. It is available in boxes of 2, 6, 8, 10, 20, 30, 40, 50, 60 or 100 sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is:

Galen Pharma Ireland Limited
Finnabair Industrial Estate
Dundalk
Co Louth
A91 P9KD
Ireland.

The manufacturer is Chanelle Medical, Loughrea, Co. Galway.

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