

## **Package leaflet: Information for the user**

### **Compound Macrogol Oral Powder Sugar Free, 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 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, pharmacist or nurse. 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.

#### **What is in this leaflet:**

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

#### **1. What Compound Macrogol Oral Powder Sugar Free is and what it is used for**

Compound Macrogol Oral Powder Sugar Free contains macrogol 3350 and the electrolytes sodium chloride, sodium hydrogen carbonate and potassium chloride.

Macrogol 3350 is a laxative used for the treatment of constipation, especially if you have been constipated for a long time. 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 help to maintain your body's normal levels of sodium, potassium and water while you are being treated for constipation.

#### **2. What you need to know before you take Compound Macrogol Oral Powder Sugar Free**

##### **Do not take Compound Macrogol Oral Powder Sugar Free:**

- if you are allergic (hypersensitive) to macrogol 3350, sodium chloride, sodium hydrogen carbonate, potassium chloride or acesulfame potassium
- if you have a perforation in the wall of your intestine
- if you have a blockage in your intestine
- if you have paralysis of the intestine (for example, your intestines may stop working due to intestinal surgery or severe infection)
- if you have ulcerative colitis, Crohn's disease or toxic megacolon

If any of these applies to you, please talk to your doctor, pharmacist or nurse for further advice.

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Compound Macrogol Oral Powder Sugar Free to treat faecal impaction, as prior to taking this medicine it should be confirmed that you have this condition.

When taking Compound Macrogol Oral Powder Sugar Free you should continue to take plenty of fluids. The fluid content of Compound Macrogol Oral Powder Sugar Free should not replace your regular liquid intake.

### **Other medicines and Compound Macrogol Oral Powder Sugar Free**

Some medicines, e.g. anti-epileptics, may not work as effectively if they are taken at the same time as Compound Macrogol Oral Powder Sugar Free. Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. You should not take any other medicines by mouth for one hour before and for one hour after taking Compound Macrogol Oral Powder Sugar Free.

If you need to thicken fluids in order to swallow them safely, Compound Macrogol Oral Powder Sugar Free may counteract the effect of the thickener.

### **Compound Macrogol Oral Powder Sugar Free with food and drink**

Food and drink have no influence on the effect of Compound Macrogol Oral Powder Sugar Free.

### **Pregnancy and breast-feeding**

Compound Macrogol Oral Powder Sugar Free 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**

Compound Macrogol Oral Powder Sugar Free has no effect on the ability to drive or use machines.

### **Compound Macrogol Oral Powder Sugar Free contains potassium and sodium**

Compound Macrogol Oral Powder Sugar Free contains 0.68mmol (26mg) of potassium per sachet. This should be taken into consideration if you take more than one sachet daily and you have reduced kidney function, or if you are on a controlled potassium diet.

This medicine contains 187mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to approximately 9% of the recommended maximum daily dietary intake of sodium for an adult.

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.

### **3. How to take Compound Macrogol Oral Powder Sugar Free**

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure. Compound Macrogol Oral Powder Sugar Free should be taken orally.

Compound Macrogol Oral Powder Sugar Free is a laxative for the treatment of constipation and faecal impaction in adults, children (aged 12 years and above) and the elderly.

#### **Constipation**

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

#### **Faecal impaction**

The usual dose for faecal impaction is eight sachets daily. All eight sachets must be taken within a six hour period. If you have a heart condition, do not take more than two sachets (in 250ml of water) in any one hour.

#### **How to mix**

Compound Macrogol Oral Powder Sugar Free should be made up by dissolving the contents of one sachet in a glass of water (125ml or a quarter pint). Stir well until all the powder has dissolved. 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).

#### **Duration of treatment**

##### **Constipation**

The course of treatment for constipation does not normally last longer than 2 weeks. Your treatment may last for longer than two weeks if you have ongoing constipation, or a disease that causes constipation (such as Parkinson's disease or multiple sclerosis), or if you are taking other regular medicines that can cause constipation. In these cases, your doctor may reduce your dose to one sachet taken one or two times daily.

##### **Faecal impaction**

The course of treatment for faecal impaction does not normally last longer than 3 days.

#### **If you take more Compound Macrogol Oral Powder Sugar Free than you should**

You may experience severe pains and swelling in your abdomen, or vomiting or diarrhoea, which can lead to dehydration. If this occurs, stop taking Compound Macrogol Oral Powder Sugar Free and drink plenty of fluids. If you are worried contact your doctor or pharmacist.

#### **If you forget to take Compound Macrogol Oral Powder Sugar Free**

If you forget to take a dose, take it as soon as you remember and then continue on as before. Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking Compound Macrogol Oral Powder Sugar Free**

To get the most benefit from Compound Macrogol Oral Powder Sugar Free, always finish the course of treatment recommended by your doctor or pharmacist. 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 after 14 days for chronic constipation, or after 3 days for faecal impaction.

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

#### **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 Compound Macrogol Oral Powder Sugar Free and see your doctor immediately:

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

The following side effects are also possible:

- abdominal pain
- feeling bloated
- suffering from wind
- indigestion
- soreness of the anus (bottom)
- mild diarrhoea
- nausea
- vomiting
- swelling of your abdomen
- stomach rumbling

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme:

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Compound Macrogol Oral Powder Sugar Free**

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

You should store unopened sachets below 25°C.

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

Reconstituted Compound Macrogol Oral Powder Sugar Free solution can be covered and stored in the refrigerator (2°C to 8°C), and should be used within six hours. After six hours, any unused solution should be discarded.

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 Compound Macrogol Oral Powder Sugar Free contains**

The active substances are macrogol 3350 (13.125g), sodium chloride (350.7mg), sodium hydrogen carbonate (178.5mg) and potassium chloride (46.6mg). Compound Macrogol Oral Powder Sugar Free also contains acesulfame potassium (E950).

### **What Compound Macrogol Oral Powder Sugar Free looks like and contents of the pack**

Compound Macrogol Oral Powder Sugar Free is a white powder that is packed in sachets.

Each sachet contains 13.7g of powder and is packed in cartons containing 2, 8, 10, 20, 30, 50 and 100 sachets. Not all of these pack sizes are marketed.

### **Marketing Authorisation Holder**

Galen Limited  
Seagoe Industrial Estate  
Craigavon  
BT63 5UA  
UK

### **Manufacturer**

Almac Pharma Services Limited  
Almac House  
20 Seagoe Industrial Estate  
Craigavon  
BT63 5QD  
UK

Almac Pharma Services (Ireland) Limited  
Finnabair Industrial Estate

Dundalk  
Co Louth  
A91 P9KD  
Ireland

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

Belgium – Laxido Natuur/Nature

Germany – Laxido Natural

Luxembourg – Laxido Nature

Finland, Ireland and Sweden – Laxido

United Kingdom (Northern Ireland) – Compound Macrogol Oral Powder Sugar Free

**This leaflet was last revised in 09/2021.**