

**Package Leaflet: Information for the user**  
**Laxido Paediatric Plain, 6.9 g sachet, powder for oral solution**

**Read all of this leaflet carefully before you give this medicine to your child because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask the doctor, pharmacist or nurse.
- This medicine has been prescribed for your child. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets any side effects, talk to their 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 Laxido Paediatric Plain is and what it is used for
2. What you need to know before you give Laxido Paediatric Plain
3. How to give Laxido Paediatric Plain
4. Possible side effects
5. How to store Laxido Paediatric Plain
6. Contents of the pack and other information

**1. What Laxido Paediatric Plain is and what it is used for**

Laxido Paediatric Plain contains macrogol 3350 and the electrolytes sodium chloride, sodium hydrogen carbonate and potassium chloride.

Laxido Paediatric Plain is a laxative used for the treatment of chronic constipation in children aged 1 to 11 years. It is also used to treat a build up of hard faeces in the bowel in children aged 5 to 11 years, which may be a result of long-term constipation (this is known as faecal impaction). Macrogol 3350 makes your child's faeces softer and easier to pass, giving them relief from constipation. The electrolytes help to maintain the body's normal levels of sodium, potassium and water while your child is being treated for constipation.

**2. What you need to know before you give Laxido Paediatric Plain**

**Do not give Laxido Paediatric Plain if your doctor has told you that your child:**

- is allergic to macrogol 3350, sodium chloride, sodium hydrogen carbonate or potassium chloride
- has a perforation in the wall of their intestine
- has a blockage in their intestine
- has paralysis of the intestine (for example, your child's intestines may stop working due to intestinal surgery or severe infection)
- has ulcerative colitis, Crohn's disease or toxic megacolon.

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

### **Warnings and precautions**

Before giving Laxido Paediatric Plain to your child for faecal impaction, it should be confirmed by their doctor that your child has this condition.

If your child has a heart or kidney problem, an impaired gag reflex, reflux oesophagitis (heartburn caused by back-flow of stomach contents in the oesophagus) or reduced consciousness, you should talk to their doctor before giving Laxido Paediatric Plain.

When taking Laxido Paediatric Plain you should continue to take plenty of fluids. The fluid content of Laxido Paediatric Plain should not replace your regular liquid intake.

### **Other medicines and Laxido Paediatric Plain**

Tell their doctor or pharmacist if your child is taking, has recently taken, or might take any other medicines. Some medicines, e.g. anti-epileptics, may not work as effectively if they are taken at the same time as Laxido Paediatric Plain. When taking large volumes of Laxido Paediatric Plain (e.g. for faecal impaction), your child should not take other medicines within one hour of taking Laxido Paediatric Plain.

If you need to thicken fluids in order to swallow them safely, Laxido Paediatric Plain may counteract the effect of the thickener.

### **Laxido Paediatric Plain with food, drink and alcohol**

Food and drink have no influence on the effect of Laxido Paediatric Plain.

### **Pregnancy, breast-feeding and fertility**

Laxido Paediatric Plain can be given during pregnancy and whilst breast-feeding. Ask your pharmacist or doctor for advice before giving Laxido Paediatric Plain.

### **Driving and using machines**

Laxido Paediatric Plain has no effect on the ability to drive or use machinery.

### **Laxido Paediatric Plain contains potassium and sodium**

This medicine contains 0.34 mmol (13 mg) of potassium per sachet. This should be taken into consideration if you give your child more than three sachets daily and they have reduced kidney function or if they are on a controlled potassium diet.

This medicine contains 93 mg of sodium (main component of cooking/table salt) in each sachet. This is equivalent to approximately 4.6% of the recommended maximum daily dietary intake of sodium for an adult.

## **3. How to give Laxido Paediatric Plain**

Always give this medicine exactly as the doctor or pharmacist has told you. Check with the doctor or pharmacist if you are not sure. Laxido Paediatric Plain should be taken orally.

### **Chronic constipation**

The recommended dose for chronic constipation depends on the age of the child and their response to treatment.

- As a starting dose, children aged 1 to 6 years should be given 1 sachet each day and children aged 7 to 11 years should be given 2 sachets each day.
- The doctor may tell you to increase the number of sachets taken until your child has a soft bowel movement.

If the dose does need increasing, this should be done every other day. For children below 2 years of age, no more than 2 sachets should be taken in one day. For children 2 to 11 years, normally, no more than 4 sachets are required to be taken in one day.

It is not necessary to take all of the drink at one time, if the child prefers it, half the drink can be taken in the morning and half in the evening.

### **Faecal impaction**

A course of treatment with Laxido Paediatric Plain is as follows:

Number of Laxido Paediatric Plain sachets							
Age (years)	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
5 to 11	4	6	8	10	12	12	12

The daily number of sachets should be taken in divided doses, all taken within 12 hours (e.g. 8am to 8pm). Treatment can be stopped when the medicine has worked. This is shown by your child passing large volumes of stool and/or watery diarrhoea.

### **How to mix**

Laxido Paediatric Plain should be made up by dissolving the contents of one sachet in a quarter glass of water (62.5 ml). Stir well until all the powder has dissolved and the Laxido Paediatric Plain solution is clear or slightly hazy, then give it to your child to drink. If you like you can add a flavour such as orange squash to the drink. If your child is taking Laxido Paediatric Plain for faecal impaction it may be easier to dissolve 12 sachets in 750 ml of water. In this case, the reconstituted solution must be stored in accordance with the relevant instructions provided in section 5.

### **Duration of treatment**

#### **Chronic constipation**

The course of treatment for chronic constipation needs to be for a prolonged period of time, at least 6 to 12 months.

#### **Faecal impaction**

The course of treatment for faecal impaction can be for up to 7 days.

### **If your child takes more Laxido Paediatric Plain than they should**

Your child may experience severe pains and swelling in their abdomen, or vomiting or diarrhoea. If this happens, contact their doctor or pharmacist.

**If you forget to give Laxido Paediatric Plain**

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

**If you stop giving Laxido Paediatric Plain**

To get the most benefit from Laxido Paediatric Plain, always make sure that your child finishes the course of treatment recommended by their doctor, pharmacist or nurse. This will make sure that your child's constipation is cleared, otherwise the symptoms they are suffering from may persist.

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

**4. Possible side effects**

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

If your child experiences any of the following side effects, stop giving Laxido Paediatric Plain and see their 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 the fluid or electrolyte levels in your child's body, 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 child's blood are higher or lower than normal.

The following side effects are most common:

- abdominal pain
- stomach rumbling
- diarrhoea
- vomiting
- nausea
- soreness of the anus (bottom)

If your child is being treated for chronic constipation, diarrhoea will usually improve when the dose is reduced.

The following side effects are less common:

- swelling of your child's abdomen
- suffering from wind
- indigestion

**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 HPRA Pharmacovigilance; website: [www.hpra.ie](http://www.hpra.ie)

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

## **5. How to store Laxido Paediatric Plain**

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.

Reconstituted Laxido Paediatric Plain solution can be covered and stored in the refrigerator (2 °C to 8 °C), and should be used within 24 hours. After 24 hours, any unused solution should be discarded.

Do not use this medicine if you notice that any of the sachets are 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 Laxido Paediatric Plain contains**

The active substances in each sachet are macrogol 3350 (6.563 g), sodium chloride (175.4 mg), sodium hydrogen carbonate (89.3 mg) and potassium chloride (25.1 mg).

Laxido Paediatric Plain does not contain any other ingredients. It does not contain any colours, flavours or sweeteners.

### **What Laxido Paediatric Plain looks like and contents of the pack**

Laxido Paediatric Plain is a white powder for oral solution that is packed in sachets.

Each sachet contains 6.9 g of powder and is packed in cartons containing 2, 6, 8, 10, 20, 30, 50 and 100 sachets. Not all of these pack sizes are marketed.

### **Marketing Authorisation Holder**

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

### **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:**

Ireland and United Kingdom (Northern Ireland) – Laxido Paediatric Plain  
Portugal – Laxido Mini  
Belgium and Luxembourg – Laxido Junior Neutral  
Sweden – Laxido Junior

**This leaflet was last revised in September 2021.**