

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Laevolac Plum 10 g/15 ml oral solution

Lactulose

#### **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 has 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 after 3 days.

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

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

#### **1. What Laevolac Plum is and what it is used for**

Laevolac Plum contains the active substance lactulose, it is not absorbed into your body and reaches the colon unchanged. Lactulose is a laxative and a prebiotic substance that supports the growth acidophilic bacteria (e.g. lactobacilli) present in the colon. This makes the stool softer and easier to pass, by drawing water into the bowel.

Laevolac Plum is used to treat the symptoms of constipation.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

#### **2. What you need to know before you take Laevolac Plum**

##### **Do not take Laevolac Plum:**

- if you are allergic to lactulose or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from
  - galactosaemia (a severe genetic disorder where you cannot digest galactose),
  - acute inflammatory bowel disease (like Crohn's disease or ulcerative colitis) blockage in your bowel (apart from normal constipation), a hole in your stomach or bowel or risk of a hole in your stomach or bowel, abdominal pain for which no cause has been found.

#### **Warnings and Precautions**

Talk to your doctor or pharmacist before taking Laevolac Plum.

Please tell your doctor before taking Laevolac Plum if you suffer from gastro-cardiac syndrome (Roemheld syndrome). If you have symptoms like excess gas in your bowels or bloating after using it, stop the treatment and consult your doctor. In these cases your doctor will supervise the treatment carefully.

Longterm use of unadjusted dosages (exceeding 2 - 3 soft stools per day) or misuse can lead to diarrhoea and disturbance of the electrolytes balance.

If you are an elderly patient or a patient in bad general condition and take lactulose for a more than 6 months period, your doctor will regularly check your blood electrolytes.

Please do not use Laevolac Plum without medical advice for more than two weeks.

During the treatment with laxatives you should drink sufficient amounts of fluids (approx. 1.5 - 2 l / day, equal to 6 - 8 glasses).

### **Children and adolescents:**

Children and adolescents should use laxatives only under the supervision of a doctor. Laevolac Plum should not normally be given to toddlers and infants as it can disturb the normal reflexes for passing stools.

In special circumstances your doctor may prescribe Laevolac Plum for a child, infant or newborn infant. In these cases your doctor will supervise the treatment carefully.

### **Other medicines and Laevolac Plum**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Lactulose may increase the loss of potassium caused by other drugs (e.g. thiazides, steroids and amphotericin B). Use of cardiac glycosides along with lactulose can increase the effect of the glycosides by decreasing potassium in the blood.

With increasing dosage a decrease of pH-value in the colon is found. Therefore drugs which are released in the colon pH-dependently (e.g. 5-ASA (5-aminosalicylate)) can be inactivated.

### **Laevolac Plum with food and drink**

Laevolac Plum can be taken with or without food. There are no restrictions on what you can eat or drink.

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

Laevolac Plum can be used during 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.

### **Driving and using machines**

Laevolac Plum has no or negligible influence on your ability to drive and use machines.

### **Laevolac Plum may contain small amounts of sugars.**

Laevolac Plum may contain small amounts of sugars (milk sugar (lactose), fruit sugar (fructose), galactose, tagatose or epilactose). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

The dose normally used should not pose a problem for diabetics. 15 ml of lactulose contain 42.7 KJ (10.2 kcal) = 0.21 BU.

## **3. How to take Laevolac Plum**

For oral use.

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

Take your doses at the same time each day. The dose may be taken once daily, for example during breakfast, or divided into two or three doses a day.

Swallow the medicine quickly. Do not keep it in your mouth.

You can take Laevolac Plum oral solution undiluted or diluted in some liquid.

During the treatment with laxatives you should drink sufficient amounts of fluids (approx. 1.5 - 2 l / day, equal to 6 - 8 glasses).

If diarrhoea occurs, the dose should be reduced.

For a precise dosing for infants, toddlers and children up to 6 years, lactulose is available in bottles.

The recommended dose is:

For constipation or where a soft stool is considered of medicinal benefit:

	Starting dose		Maintenance dose	
Adults	15 - 45 ml daily	1-3 sachets, corresponding to 10-30 g lactulose	15-30 ml daily	1-2 sachets, corresponding to 10 - 20 g lactulose

In elderly patients ( $\geq 65$  years) and patients with renal or hepatic insufficiency no special dosage recommendations exist.

#### Use in children and adolescents:

Please do not give Laevolac Plum to children and adolescents < 14 years before consulting your doctor for prescription and careful supervision.

The recommended dose is:

For constipation or where a soft stool is considered of medicinal benefit:

	Starting dose		Maintenance dose	
Adolescents over 14 years	15 - 45 ml daily	1 - 3 sachets, corresponding to 10 - 30 g lactulose	15 - 30 ml daily	1 - 2 sachets, corresponding to 10 - 20 g lactulose
Children and adolescents (7 - 14 years)	15 ml daily	1 sachet, corresponding to 10 g lactulose	15 ml daily	1 sachet, corresponding to 10 g lactulose

#### Treatment duration:

The duration of treatment has to be adopted according to the symptoms. It can take 2 - 3 days until the desired effect will be achieved since lactulose is not degraded until it reaches the colon.

#### **If you take more Laevolac Plum than you should**

In case of overdosage, you may experience diarrhoea and abdominal pain. Contact your doctor or pharmacist if you have taken more Laevolac Plum than you should.

#### **If you forget to take Laevolac Plum**

If you forget to take a dose of Laevolac Plum, do not worry. Just take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking Laevolac Plum**

The desired effect of the medicine may not be achieved.

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.

The following side effects have been reported with Laevolac Plum:

- Flatulence (wind), especially during the first few days of treatment. This usually disappears after a couple of days.
- Nausea (feeling sick)
- Vomiting
- Electrolyte imbalance due to diarrhoea can be found during investigations.
- When a higher dose than recommended is used, you may experience abdominal pain and diarrhea.

The frequency of these side effects is not known, i.e. the frequency cannot be estimated from the available data.

### **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 [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Laevolac Plum**

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the outer carton/sachet after “EXP”. The expiry date refers to the last day of that month.

Partially used sachets have to be discarded.

Do not throw away any medicines via waste water 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 Laevolac Plum contains**

- The active substance is lactulose  
One sachet (15 ml) of Laevolac Plum contains 10 g lactulose (as lactulose liquid).
- The other ingredient is plum flavour. The plum flavour consists of plum extract, ethyl alcohol, propylene glycol, aromatic substance and caramel colour.

### **What Laevolac Plum looks like and contents of the pack**

Laevolac Plum is a clear, viscous liquid, colourless or pale brownish-yellow oral solution with plum odour and taste and is available in following pack sizes: 10 and 20 sachets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

{to be completed nationally}

#### **Manufacturer**

Fresenius Kabi Austria GmbH

ENG-PIL MRP SD Plum

Estermannstraße 17  
4020 Linz, Austria

<for Germany only>  
T&D Pharma GmbH  
Lengauer Straße 16  
32689 Kalletal, Germany

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Austria:	LaevoGo Pflaumenaroma 10 g/15 ml Lösung zum Einnehmen
Germany:	Laevolac Pflaumenaroma 10 g/15 ml Lösung zum Einnehmen
Ireland:	Laevolac Plum 10 g/15 ml oral solution
Italy:	Lattulosio Fresenius 10 g/15 ml soluzione orale
United Kingdom:	Laevolac plum flavour 10 g/15 ml oral solution

**This leaflet was last revised in (mm/yyyy)**