

LAEVOLAC®-ORAL SOLUTION

(Lactulose concentrate 50%w/w)

What is in this leaflet

1. What **Laevolac®-Oral Solution** is used for
2. How **Laevolac®-Oral Solution** works
3. Before you use **Laevolac®-Oral Solution**
4. How to take **Laevolac®-Oral Solution**
5. While you are using **Laevolac®-Oral Solution**
6. Side effects
7. Storage and Disposal of **Laevolac®-Oral Solution**
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What **Laevolac®-Oral Solution** is used for

Laevolac® is an aqueous 50% w/w solution of the sugar lactulose which belongs to a group of medicines known as laxatives, which ease the bowel movement

It is used for the treatment of chronic constipation -prophylaxis and therapy of hepatic encephalopathy.

How **Laevolac®-Oral Solution works**
Laevolac®-Oral Solution contains a laxative called lactulose. It makes the stool softer and easier to pass, by drawing water into the bowel. It is not absorbed into your body.

Before you use **Laevolac®-Oral Solution**

- When you must not use it

Do not take **Laevolac®**:

- if you are allergic to lactulose
- If you have any blockage in your bowel that is not due to constipation

- Before you start use it

If you are pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking any medicines

- Taking other medicines

Please inform your doctor or pharmacist if you are taking, or have recently taken any other medicine, even those not prescribed

How to use **Laevolac®-Oral Solution**

- How much to use

To take **Laevolac®** pour it out carefully into a teaspoon (corresponds to 5ml) and swallow your medicines directly from the spoon

Dosage for constipation Starting dose

Adults	30ml a day
Children 7 to 14 years	15ml a day
Children 1 to 6 years	10ml a day
Infants	5ml a day

The dose can usually be reduced after a few days and adjusted to the needs of the patient

Dosage for liver disease:

Starting dose : 30 to 50ml three times daily

In elderly patients and patients with renal or hepatic insufficiency, no special dosage recommendation exist.

- When to use it

Take **Laevolac®** with food and drink.

Laevolac® can be diluted with water or other liquid and can be taken in independence meals.

- How long to use it

The drug should preferably be taken as a single dose with breakfast. It may take a few days before the desired effect is achieved, which is inherent in the principal of action of lactulose

- If you forget to use it

Do not take a double dose to make up for forgotten individual doses

- If you use too much (overdose)

If you may have taken more **Laevolac®** than you should, talk to a doctor or pharmacist

While you are using it **Laevolac®-Oral Solution**

- Things you must do

Patients who have been experiencing constipation for a prolonged period of time should consult a doctor and be examined before starting treatment with **Laevolac®**. Chronic impairment of bowel movement may be a sign of a more serious illness

- Things you must not do

Chronic use and misuse can lead to diarrhea and disturbance of electrolyte balance

- Things to be careful of

Laevolac® contains in 15ml syrup a maximum of 2.6g digestible carbohydrates. In diabetics and patients with other utilization disorders of carbohydrates (fructose, galactose, and lactose) has to be calculated. 15ml **Laevolac®** contain 0.1g fructose, 1.5g galactose and 1.0g lactose, which corresponds approximately to 10.2 kcal/42.7 kJ respectively 0.21 BU (bread units) in a maximum

Side effects

Like all medicines, **Laevolac®** can have side effects

Most people benefit from taking **Laevolac®**, but a few people can be upset by it. Side effects that have been reported include stomach cramps, nausea, a feeling of bloatedness in the stomach and winds. However, these effects are rare and usually go away after the initial stages of treatment. Some patients have also felt sick when they have taken high doses of **Laevolac®**. The feeling of sickness may be reduced if you drink some water or fruit juice after taking your medicine or, alternatively, take your medicine at meal time

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-

78835550, or visiting the website
npra.moh.gov.my (Consumers
→Reporting).

Storage and Disposal of ORATANE Capsule

- Storage

Keep **Laevolac®** out of the reach and
sight of children

Do not store above 30°C

Do not use after the expiry stated on the
label

- Disposal

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 to protect the
environment.

Product Description

- What it looks like

Laevolac®-Oral Solution is a clear,
viscous liquid, colourless or pale
brownish-yellow solution.

- Ingredients

- Active ingredient

The active substance is lactulose.

There are no other ingredients.

- MAL number:

MAL 20033966XZ

Manufacturer

Fresenius Kabi Austria GmbH
Estermannstrasse 17, 4020 Linz
AUSTRIA

Product Registration Holder

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Date of revision

1st August 2018