

PACKAGE LEAFLET: INFORMATION FOR THE USER

Normase 667 mg/ml oral solution

Lactulose

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Normase carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 7 days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Normase is and what it is used for
2. Before you take Normase
3. How to take Normase
4. Possible side effects
5. How to store Normase
6. Further information

1. WHAT NORMASE IS AND WHAT IT IS USED FOR

Normase belongs to a group of medicines which are called laxatives. It is used to treat constipation. Normase is also used to treat hepatic encephalopathy (also known as hepatic coma).

2. BEFORE YOU TAKE NORMASE

Do not take Normase

- If you are allergic (hypersensitive) to lactulose or any of the other ingredients of Normase.
- If you have been told by your doctor that you have an intolerance to some sugars (galactose or lactose).
- If you have a blockage other than normal constipation.
- If you suffer from abdominal pain, nausea or vomit, rectal bleeding, severe dehydration.

Take special care with Normase

- If you suffer from diabetes, please consult your doctor since it may contain small amounts of other sugars.
- Before starting treatment with Normase, please consult your doctor if you are elderly or if you are ill.
- Use of Normase in children under the age of 12 years should be under medical supervision.

Taking other medicines

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

Normally, it should be avoided taking laxatives and other medicinal products at the same time: after taking a medicine, it is advisable to wait at least two hours before to take Normase.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Normase should be used under medical supervision during pregnancy or nursing.

Driving and using machines

Normase does not influence the ability to drive and use machines.

3. HOW TO TAKE NORMASE

Always follow your doctor's instruction.

The usual starting dose for constipation is:

Adults (including the elderly)	20 ml daily (a higher initial dose of 30 to 40 ml daily may be needed in some cases)
Children 6 to 12 years	5 to 7.5 ml twice daily
Children under 6 years	2.5 to 5 ml twice daily
Babies under 1 year	2.5 ml twice daily

It is advisable to use initially the minimum recommended doses. Do not exceed the maximum indicated dose.

Normase may take some days to start working. After this time you may be able to reduce the dose you take according to your needs.

The indicated dose can be taken once a day, preferably in the morning after overnight fast or in the evening before dinner. Swallow with sufficient quantity of water (a plentiful glass of water). A diet rich in liquids promotes efficacy of the medicinal product.

The usual starting dose for hepatic encephalopathy is:

Adults (including the elderly): 30-50ml three times a day

Children: there is no childrens' dosage for this indication.

If you take more Normase than you should

If you take too much Normase, you are likely to have diarrhoea. You should consult a doctor for advice.

If you forget to take Normase

If you forget to take a dose take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

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

In the first few days of taking your medicine you may feel bloated and suffer from wind or stomach cramps. These symptoms usually disappear after a few days. At high doses, you may suffer from stomach ache and diarrhoea. If this happens, reduce your dose.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE NORMASE

Do not store above 25°C.

Do not refrigerate or freeze.

Keep out of the reach and sight of children.

Do not use Normase after the expiry date which is stated on the package after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Normase contains

- The active substance is lactulose. 1 ml of Normase contains 667 mg of lactulose.
- The other ingredients are citric acid, cream flavour and purified water.

What Normase looks like and contents of the pack

Normase is a clear to almost colourless to pale brownish-yellow oral solution.

Normase is available in bottles with 200 ml of oral solution. A measuring cup graded 2.5-5-7.5-10-15 ml is provided with the bottle.

Marketing Authorisation Holder and Manufacturer

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