

DUPHALAC® SYRUP

Lactulose (667g/l)

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What Duphalac® is used for

Duphalac® is used to treat constipation (infrequent bowel movements, hard and dry stools) and hepatic encephalopathy (a liver disease causing confusion, tremor, decreased level of consciousness). Hepatic encephalopathy can lead to a hepatic coma

How Duphalac® works

Duphalac® 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 Duphalac®

- When you must not use it

Do not take Duphalac® if:

- You are allergic (hypersensitive) to lactulose or any of the other ingredients of Duphalac®
- You have a rare problem called 'galactosaemia'.
- You have a blockage caused by anything else but normal constipation, digestive perforation (ruptured bowel) or risk of it

Do not use Duphalac® if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Duphalac®.

- Before you start to use it

Talk to your doctor or pharmacist before taking Duphalac® if you suffer from any medical conditions or illnesses, in particular:

- if you suffer from unexplained tummy ache
- if you are unable to digest milk sugar (lactose intolerant)
- if you have diabetes

- Taking other medicines

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

How to use Duphalac®

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

You may take Duphalac oral solution diluted or undiluted. Take your dose of lactulose in one swallow; do not hold the solution in your mouth for any length of time.

Constipation

Adults and adolescents: The starting dose is 15-45ml per day. After this the dose can be adjusted to 15-30ml daily.

Children 7 to 14 years: The starting dose is 15ml daily. After this the dose can be adjusted to 10-15ml daily.

Children 1-6 years: The usual dose is 5-10ml daily.

Infants under 1 year: The usual dose is up to 5ml daily.

Hepatic encephalopathy

Adults: The usual starting dose is 3 to 4 times a day of 30-45ml

- When to use it

Use as directed by your doctor or pharmacist and always take it at the same time of the day.

- How long to use it

Continue taking Duphalac® for as long as your doctor or pharmacist recommends.

- If you forget to use it

Do not take a double dose to make up for the forgotten dose. Take the next dose at your regular time on the next day. If you are worried about this, talk to your doctor or pharmacist.

- If you use too much (overdose)

If you take more Duphalac® than you should stop taking Duphalac® and talk to a doctor or pharmacist. You may have diarrhoea, loss of electrolytes and abdominal pain.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

During therapy with laxatives it is important for you to drink sufficient amounts of fluids (1.5-2 litres, equal to 6-8 glasses) during the day.

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Talk to your doctor or pharmacist before taking this medicine if you are pregnant, might become pregnant or are breast-feeding. Duphalac® can be used during pregnancy and when breast-feeding if necessary.

- Things to be careful of

Duphalac® contains sugars, such as lactose, galactose and fructose. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

If Duphalac® is used for small child, you may want to take protective measures, such as using diapers.

Side effects

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

Very common (may affect more than 1 in 10 people):

Diarrhoea

Common (may affect up to 1 in 10 people)

Flatulence (wind), nausea (feeling sick), vomiting, abdominal pain

Uncommon (may affect up to 1 in 100 people)

Electrolyte imbalance due to diarrhoea

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Duphalac®

- Storage

Keep this medicine out of the sight and reach of children. Do not use Duphalac® after the expiry date which is stated on the carton and the sachet after EXP. The expiry date refers to the last day of that month. Do not store above 30°C

- 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 protect the environment.

Product Description

- What it looks like

Duphalac® is a clear, viscous liquid, colourless to brownish- yellow liquid.

Duphalac® is available in 15ml sachet (10 sachets in a pack), 200ml bottle and 500ml bottle.

- Ingredients

- Active ingredient(s)
Lactulose

- Inactive ingredients

Duphalac® does not contain any excipients, but may contain small amounts of related sugars. (e.g. lactose, galactose, fructose)

- MAL number:

Duphalac® Syrup:
MAL19921431XZ

Manufacturer

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The Netherlands

Product Registration Holder

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