

Duphalac, syrup 667 mg/ml

PACKAGE LEAFLET: INFORMATION FOR THE USER

Duphalac, syrup 667 mg /ml

Read all of this leaflet carefully before you or your child are going to use this medicinal product, because it contains important information for you and your child.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- Do not pass this medicinal product to others, as it has only been prescribed for you. It can be harmful to other persons, even if they have the same symptoms as you.
- 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.
- Please refer to your local registered prescribing information as it may differ from country to country.

In this leaflet

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1. WHAT DUPHALAC SYRUP IS and WHAT IT IS USED FOR

What Duphalac syrup is

Duphalac syrup 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.

What Duphalac is used for

Duphalac is used to treat constipation (infrequent bowel movements, hard and dry stools) and to make the stool softer, for example

- When you have haemorrhoids,
- When you had surgery on your anus or colon.

Duphalac is used to treat hepatic encephalopathy (HE) (a liver disease causing confusion, tremor, decreased level of consciousness including coma).

Duphalac is used for bowel cleansing in preparation for colonoscopy (adults).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE DUPHALAC

Do not take Duphalac if:

- You are allergic (hypersensitive) to:
 - lactulose
 - any of the other ingredients of Duphalac (listed in Section 6).
- When you suffer from:
 - galactosaemia (a serious genetic defect by which one does not digest galactose).
 - a blockage in the gastrointestinal tract caused by anything else but normal constipation.
- - digestive perforation or risk of digestive perforation
- Duphalac solution for bowel cleansing should not be administered to unconscious patients or when you have impaired consciousness, when you are prone to aspiration or regurgitation, suffer from general weakness, are severely dehydrated or have an impaired swallowing reflex.

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

Warnings and precautions

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

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

If you take Duphalac for several days and there is no improvement in your condition or if your symptoms worsen, please contact your doctor.

You should not take Duphalac if you suffer from:

- galactose or fructose intolerance
- total lactase deficiency
- glucose-galactose malabsorption

If you have diabetes and are treated for hepatic encephalopathy, your dose of Duphalac will be higher. This high dose contains a large amount of sugar. Therefore, you may need to adjust the dose of your anti-diabetic medicine.

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

During treatment of acute cases of hepatic encephalopathy with a retention enema, accidental bowel leakage (fecal incontinence) and peri-anal irritation may occur.

The hydration status of the patient should be observed carefully.

Diarrhea is an expected effect resulting from the use of lactulose for bowel cleansing in preparation for colonoscopy, esp. also in combination with bisacodyl. Should nausea, vomiting, abdominal distension or abdominal pain arise, the rate of administration should be slowed down or temporarily stopped until symptoms subside. In certain patients at risk, e.g. elderly or debilitated patients, patients with clinically significant renal impairment, careful monitoring of the electrolyte and fluid balance is required.

Other medicines and Duphalac

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

Up to several hours before, during or up to one hour after taking Trademark solution for bowel cleansing, as with other bowel cleansing regimens, orally administered medicines may possibly be washed out of the gastrointestinal tract or may not, or only partially, be absorbed.

If administration of a medicine is absolutely necessary for a life-threatening indication shortly before or whilst taking the treatment regimen for bowel cleansing, oral administration may have to be withheld and a switch made to an alternative. The concomitant use of other laxatives (bisacodyl) may enhance the gastrointestinal side effects of lactulose.

Taking Duphalac with food and drink

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

Pregnancy, breast-feeding and fertility

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.

No effects on fertility are to be expected.

Children

In special circumstances your doctor may prescribe Duphalac for a child, infant or baby. In these cases, your doctor will supervise the treatment carefully. Duphalac should only be given to infants and smaller children if indicated as it can influence the normal reflexes for passing stools.

Driving and using machines

Duphalac has no or negligible influence on your ability to drive safely or use machines.

Important information about some of the ingredients of Duphalac

Duphalac syrup may contain small amounts of milk sugar (lactose), galactose, epilactose or fructose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE DUPHALAC

Always take Duphalac exactly as described in this leaflet or as your doctor or pharmacist have told you.

Check with your doctor or pharmacist if you are not sure.

Take your dose at a fixed moment during the day. Swallow the dose immediately. Do not keep it in your mouth.

You can take Duphalac undiluted or diluted with another liquid.

For Duphalac syrup in bottles, the measuring cup can be used.

For Duphalac syrup in 15 ml single dose sachets, tear off the corner of the sachet and consume the content immediately.

Dosing for constipation or for obtaining a soft stool for medical reasons

Lactulose may be given as a single daily dose, for example during breakfast, or divided into two doses; for Duphalac syrup in bottles, the measuring cup can be used.

Based on the response to the treatment, after a few days the initial dose may be adjusted to the maintenance dose. Duphalac may take 2 to 3 days to start working.

Duphalac syrup in bottles or 15 ml single dose sachets:

Patient Starting dose per day (in ml) Maintenance dose per day (in ml)

Adults and adolescents 15-45 ml (10-30 g lactulose),
equivalent to 1-3 sachets

15-30 ml (10-20 g lactulose),
equivalent to 1-2 sachets

Children (7-14 years) 15 ml (10 g lactulose),
equivalent to 1 sachet

10-15 ml (7-10 g lactulose),
equivalent to 1 sachet*

Children (1-6 years) 5-10 ml (3-7 g lactulose) 5-10 ml (3-7 g lactulose)

Infants under 1 year up to 5 ml (up to 3 g lactulose) up to 5 ml (up to 3 g lactulose)

*If the maintenance dose is less than 15 ml, Duphalac syrup in bottles should be used.

Use Duphalac syrup in bottles for an accurate dosage for infants and children up to 7 years.

Use in Children

Use of laxatives in children, infants, and babies should be exceptional and under medical supervision because it can influence the normal reflexes for passing stools.

Please do not give Duphalac to children under 14 years before consulting your doctor for prescription and careful supervision.

Dosage in hepatic encephalopathy (for adults only):

Oral administration:

The starting dose is 30 to 45 ml syrup, three-four times a day. This dose can be adjusted individually to a maintenance dose so that a maximum of 2 to 3 soft stools are produced per day.

Rectal administration:

In acute cases of hepatic encephalopathy, such as impending coma or coma stage, Duphalac syrup can also be administered diluted with water as a retention enema (300ml Duphalac/700ml water) until oral medication is possible again. The enema is to be retained for 30-60 minutes; the procedure is to be repeated every 4-6 hrs until oral medication can be administered.

Use in children

No information is available for treatment of children (newborn to 18 years of age) with hepatic encephalopathy.

Use in elderly patients and patients with renal or hepatic insufficiency

No special dosage recommendations exist, since systemic exposure to lactulose is negligible.

For bowel cleansing (for adults only):

A course of treatment consists of taking 10mg of bisacodyl in the evening before the examination and 1 liter of trademark solution six hours before colonoscopy. Duphalac should be diluted by diluting 200ml Duphalac in 800ml of water or lemon juice (the addition of lemon juice is to make the solution less sweet, should the sweetness impair palatability). When using lactulose and bisacodyl for bowel cleansing in preparation for colonoscopy, respective warnings, precautions and safety information from corresponding bisacodyl label needs to be taken into consideration.

Safety in the paediatric population for bowel cleansing has not been extensively established.

If you take more Duphalac than you should

If you take more Duphalac than you should, you may have diarrhoea and abdominal pain. Talk to your doctor or pharmacist if you have used too much Duphalac. Extensive fluid loss by diarrhea or vomiting may require correction of electrolyte disturbances.

If you forget to take Duphalac

If you forget a dose of Duphalac, 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 Duphalac

Do not stop or change the treatment before talking to your doctor.

If you have any further questions about using this medicine, talk to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

The following side effects have been reported with Duphalac syrup:

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

Flatulence may occur during the first few days of treatment. As a rule it disappears after a few days. When dosages higher than instructed are used, abdominal pain and diarrhoea may occur. In such a case the dosage should be decreased.

If any of these side effects worsen, or if you experience a side effect that is not listed in this leaflet, talk to your doctor or pharmacist.

If you use high doses (normally only associated with hepatic encephalopathy, HE) for an extended period of time, you may experience an electrolyte imbalance due to diarrhoea.

For Bowel cleansing:

Diarrhea is an expected outcome of bowel preparation. Due to the nature of the intervention, undesirable effects occur during the process of bowel preparation. Nausea, vomiting, abdominal distension, abdominal pain has been observed in patients undergoing bowel preparation, and these undesirable effects were also observed in the clinical studies with lactulose for bowel preparation. Undesirable effect data were actively elicited in clinical studies regarding lactulose for bowel preparation. The mainly observed undesirable effects are gastrointestinal in nature.

Reporting of side effects

If you get any side effects, talk you your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DUPHALAC

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

There are no special storage conditions for this product.

Do not use Duphalac after the expiry date which is stated on the carton or bottle. The expiry date refers to the last day of that month.

This expiry date also applies after first opening of the packaging of the bottles and container.

Sachets which were only partially used, should be disposed.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Duphalac contains

The active substance in Duphalac is lactulose. Each 5ml of Duphalac contains 3.335g of lactulose.

Each sachet of Duphalac syrup contains 15 ml, with 10 g of lactulose.

Each ml of Duphalac contains 667 mg lactulose.

Duphalac does not contain any other ingredients. However, it may contain small amounts of other Sugars from the manufacture process such as lactose, galactose, epilactose and fructose.

What Duphalac looks like and contents of the pack

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

Duphalac is available in sachets of 15 ml, in bottles containing 200ml, 300 ml, 500 ml or 1 l.

This information is confidential to Abbott. The user is responsible for using the appropriate version of this document.

Abbott
Lactulose
Nov 2019

Not all pack sizes may be marketed.

For any further information about this medicine you may contact the local representative of the Marketing Authorization Holder.