PACKAGE LEAFLET: INFORMATION FOR THE USER

# DUPHALAC

3.335g/5ml Solution

LACTULOSE

*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

## What is in this leaflet?


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


## *1. WHAT DUPHALAC IS AND WHAT IT IS USED FOR*

### *What Duphalac is*

• 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.

What Duphalac is used for

• Duphalac is used to treat constipation (infrequent bowel movements, hard and dry stools).

• Duphalac is used to treat hepatic encephalopathy (a liver disease causing confusion, tremor, decreased level of consciousness including coma). This is also known as a 'hepatic coma'.

## *2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DUPHALAC*

### *Do not take Duphalac if:*

• You are allergic (hypersensitive) to lactulose or any of the other ingredients of Duphalac (listed in Section 6).

• You have a rare problem called 'galactosaemia'.

• You have a blockage caused by anything else but normal constipation, digestive perforation or risk of digestive perforation.

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

You should not take Duphalac if you suffer from:

- galactose or fructose intolerance
- Lapp 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, your doctor may recommend that you 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 electrolytes balance.

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.

### *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.

### *Other medicines and Duphalac*

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

### *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.

### *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 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.

### *Taking this medicine*

- Take Duphalac from a spoon or measuring cup.
- You can mix it with fruit juice or water. It is recommended that you drink plenty of fluids (approximately 6-8 glasses throughout the day)
- Swallow the dose immediately. Do not keep it in your mouth as the sugar content may lead to tooth decay, particularly if Duphalac is taken for long periods.
- Duphalac takes 2 to 3 days to start working.
- After this time you may be able to reduce the dose you take according to your needs.

### *Constipation*

Adults and adolescents: The starling dose is 15-45ml or 1-3 sachets per day. After this the dose can be adjusted to 15-30ml or 1-2 sachets daily.
Children 7 to 14 years: The starting dose is 15ml or 1 sachet daily. After this the dose can be adjusted to 10-15ml or 1 sachet daily.
Children 1 to 6 years: The usual dose is 5-10ml daily.
Infants under 1 year: The usual dose is up to 5ml daily.
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.
Hepatic encephalopathy (adults only)
Adults: The usual starting dose is 3 to 4 times a day of 30-45ml or 2-3 sachets.
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.

### *If you take more Duphalac than you should*

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

### *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 on the use of this product, ask 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:

**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 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.

### *Reporting of side effects*

If you get any side effects, talk to you 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.
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.
Do not store above 25°C. Do not refrigerate or freeze.
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. 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.
- Duphalac does not contain any other ingredients. However, it may contain small amounts of other sugars, 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 plastic bottles containing 200ml.

### *Manufacturer*

Abbott Biologicals B.V.
8121 AA, Olst
The Netherlands

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### *Remember*

This medicine is for you. Please do not offer it to your family and friends, even if they have the same symptoms as you.

Duphalac contains a laxative called lactulose.
Each 5ml of Duphalac contains 3.335g of lactulose.
Duphalac contains lactose, galactose and small amounts of fructose (all are types of sugar).
If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

Read the package leaflet before use.
Keep out of the reach and sight of children.
Do not use Duphalac after the expiry date on the bottle.
Do not store above 25°C. Do not refrigerate or freeze.

This medicine is available without prescription. Duphalac is used to treat constipation. It is also sometimes used to treat a liver problem called 'hepatic encephalopathy'.
This is also known as a 'hepatic coma'.