

## Duphalac®

Lactulose 10.0 g/15 mL Oral Liquid

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about DUPHALAC.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

#### What DUPHALAC is used for

DUPHALAC belongs to a group of medicines known as laxatives.

DUPHALAC is used to treat chronic constipation. It can be taken by pregnant women.

It works by increasing the amount of water and stool bulk in the bowel, promoting normal bowel activity.

DUPHALAC can also be used to treat portal-systemic encephalopathy (PSE), also known as hepatic encephalopathy (a disease of the brain that occurs when the liver is not working properly). Symptoms are caused by too much ammonia in the blood). It works by lowering the level of ammonia in the blood.

DUPHALAC can be used where a soft stool is considered of medical benefit (haemorrhoids, anal surgery).

Ask your doctor or pharmacist if you have any questions about why DUPHALAC has been prescribed or recommended for you.

Your doctor or pharmacist may have prescribed or recommended DUPHALAC for another reason.

There is no evidence that DUPHALAC is addictive.

#### Before you take DUPHALAC

##### *When you must not take it*

**Do not take DUPHALAC if you:**

- Are allergic to lactulose, galactose, lactose or any other sugar.
- Have galactosaemia
- Have a disaccharidase deficiency
- Are on a low-galactose or galactose-free diet
- Are on a lactose-free diet
- Have a bowel obstruction (blockage other than normal constipation)

**Do not take DUPHALAC after the expiry date printed on the label or if the cap seal is broken.**

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking DUPHALAC, talk to your doctor or pharmacist.

##### *Before you start to take it*

**Tell your doctor or pharmacist if you have allergies to:**

- any other medicines.
- any other substances, such as foods, preservatives or dyes.

**Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:**

- painful abdominal symptoms with no identifiable cause
- diabetes
- lactose intolerance.

**Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.**

Your doctor or pharmacist will discuss the possible risks and benefits of using DUPHALAC during breastfeeding.

DUPHALAC has no or minor influence on the ability to drive and use machines.

**If you have not told your doctor or pharmacist about any of the above, tell them before you start taking DUPHALAC.**

##### *Taking other medicines*

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

#### How to take DUPHALAC

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions, ask your doctor or pharmacist for help.**

##### *How much to take*

###### **Chronic Constipation**

The usual starting dose for constipation in adults is 15 to 45 mL daily, and the maintenance dose is 15 to 30 mL daily.

It may take 1-2 days for DUPHALAC to work fully.

DUPHALAC should be given to children and infants under medical supervision. The usual doses are:

###### **Infants under 1 year:**

Initial dose (first 3 days): 5 mL daily

Maintenance dose: 5 mL daily

###### **Children 1-6 years:**

Initial dose (first 3 days): 5 to 10 mL daily

Maintenance dose: 5 to 10 mL daily

###### **Children 7-14 years:**

Initial dose (first 3 days): 15 mL daily

Maintenance dose: 10 to 15 mL daily

As a general rule, patients with constipation should drink plenty of water and increase the amount of fibre in their diet.

###### **Portal-Systemic Encephalopathy**

The usual dose is 30 to 45 mL three to four times daily.

##### *How to take it*

DUPHALAC is a clear liquid to be swallowed. Swallow the medicine quickly. Do not keep it in your mouth.

Using a medicine measure will ensure you get the correct dose.

Duphalac may be taken diluted or undiluted.

##### *When to take it*

DUPHALAC is best taken at the same time each day, preferably at breakfast time.

Follow the instructions given to you by your doctor or pharmacist.

##### *How long to take it*

Prolonged use of laxatives is undesirable. If symptoms persist, seek medical advice.

Continue taking DUPHALAC for as long as your doctor or pharmacist tells you.

##### *If you forget to take it*

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking DUPHALAC as you would normally.

**Do not take a double dose to make up for the dose that you missed.**

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

##### *If you take too much (overdose)*

**Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 131126), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much DUPHALAC. Do this even if there are no signs of discomfort or poisoning.**

Symptoms of an overdose are likely to be diarrhoea and abdominal cramps.

#### While you are taking DUPHALAC

##### *Things you must do*

Tell any other doctors, dentists, pharmacists or other healthcare professionals such as naturopaths, who are treating you that you are taking DUPHALAC.

If you are about to be started on any new medicine, tell your doctor, dentist, pharmacist or other healthcare professional that you are taking DUPHALAC.

**If you need to have a colonoscopy or proctoscopy, tell your doctor that you are taking DUPHALAC.**

##### *Things you must not do*

**Do not take DUPHALAC to treat any other complaints unless your doctor or pharmacist tells you to.**

#### Side effects

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DUPHALAC.**

DUPHALAC helps most people with chronic constipation, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Ask your doctor or pharmacist to answer any questions you may have.**

During the first few days of taking DUPHALAC, you may feel bloated as a result of increased wind and intestinal cramps. These effects are usually mild and disappear after a few days.

At high doses you may suffer diarrhoea. If this happens, reduce the dose and/or tell your doctor or pharmacist.

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- nausea
- vomiting

These side effects are uncommon.

Very rarely, infants given DUPHALAC may develop dehydration.

**Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Some of these side effects (for example, potassium levels in the blood) can only be found when your doctor orders blood tests.

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## After using DUPHALAC

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### *Storage*

Keep DUPHALAC in a cool place where the temperature stays below 25°C. Do not store DUPHALAC in the refrigerator or freezer.

Do not store DUPHALAC or any other medicine in the bathroom or near a sink.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### *Disposal*

If your doctor or pharmacist tells you to stop taking DUPHALAC or the liquid has passed the expiry date, ask your pharmacist what to do with any that is left over.

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## Product description

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### *What it looks like*

DUPHALAC is a clear to brownish yellow liquid.

DUPHALAC is available in 200 mL and 500 mL bottles.

### *Ingredients*

Each 15 mL of Duphalac contains 10 g lactulose as the active ingredient, furthermore 1.5 g or less of galactose, 0.9 g or less of lactose, 0.7 g or less of epilactose, 0.3 g or less of tagatose, and 0.1 g or less of fructose.

### *Sponsor*

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