

PACKAGE LEAFLET: INFORMATION FOR THE USER

**Duphalac® 3.335 g / 5 ml oral solution
lactulose**

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

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

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after several days.

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 or prevent 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 (see sections 2 and 6).
- if you suffer from
 - galactosaemia (a severe genetic disorder where you cannot digest galactose)
 - blockage in your gastrointestinal tract (apart from normal constipation)
 - gastrointestinal perforation or risk of gastrointestinal perforation (damage/puncture to the gastric and/or intestinal wall)

If you are not sure, talk to your doctor or pharmacist before taking Duphalac.

Warnings and precautions

Talk to your doctor, pharmacist or nurse 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
- total lactase deficiency
- glucose-galactose malabsorption

The usual dose of Duphalac in constipation is unlikely to affect diabetics.

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.

Duphalac can influence the normal reflexes for passing stools.

Chronic use of unadjusted dosages (exceeding 2-3 soft stools per day) or misuse can lead to diarrhoea and disturbance of the electrolyte balance. If you are prone to develop electrolyte disorders (e.g. patients with renal or hepatic impairment, patients receiving concomitant diuretics) talk to your doctor or pharmacist before taking Duphalac.

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 (2 to 3 days) and there is no improvement in your condition or if your symptoms worsen, please contact your doctor. Please do not use Duphalac for longer without medical advice.

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.

Other medicines and Duphalac

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

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

Duphalac can be used during pregnancy and breast-feeding.

No effects on fertility are to be expected.

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

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 contains sugars, e.g. milk sugar (lactose), fructose or galactose. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

Duphalac contains sulphite.

3. HOW TO TAKE DUPHALAC

Always take Duphalac exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

Take your doses at the same time each day

Swallow the medicine quickly. Do not keep it in your mouth.

You can take Duphalac oral solution undiluted or diluted in some liquid.

Dosing in Constipation

The dose may be given once daily, for example during breakfast, or divided into two doses a day, by using the measuring cup to accurately administer the appropriate dose of Duphalac.

After a few days, the starting dosage may be adjusted to the maintenance dose based upon your treatment response. Several days (2-3 days) of treatment may be needed before treatment effect occurs.

Patient	Starting dose daily	Maintenance dose
Adults and adolescents	15 – 45 ml	15 – 30 ml
Children (7-14 years)	15 ml	10 – 15 ml
Children (1-6 years)	5 – 10 ml	5 – 10 ml
Infants under 1 year	Up to 5 ml	Up to 5 ml

Use in Children

Use of laxatives in children, infants, and babies should be exceptional and under medical supervision.

Please do not give Dupliclax to children (14 years or under) before consulting your doctor for prescription and careful supervision.

Dosing in Hepatic Encephalopathy

Adults: The starting dose for hepatic encephalopathy is 30 to 45 ml oral solution, given 3 to 4 times a day. The dose may be adjusted to the maintenance dose to achieve 2 to 3 stools per day.

Use in Children and Adolescents

No data is available for treatment of children and adolescents (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 Dupliclax than you should

In case of overdose, you may experience diarrhea, loss of electrolytes and abdominal pain. Contact your doctor or pharmacist if you have taken more Dupliclax than you should.

If you forget to take Dupliclax

If you forget to take a dose of Dupliclax, 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 Dupliclax

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

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects have been reported with this medicine:

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

Frequency not known (frequency cannot be estimated from the available data)
Allergic reactions, rash, itching, hives

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 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 your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. 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 sight and reach of children.
- Do not use this medicine after the expiry date, which is stated on the bottle. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Duphalac contains

The active substance is lactulose. 5 ml of Duphalac contains 3.335 g of lactulose. Duphalac does not contain any excipients.

Duphalac contains residues from the route of production, see section 2.

What Duphalac looks like and contents of the pack

- Duphalac oral solution is a clear, viscous liquid, colourless to brownish yellow.
- Duphalac oral solution is available in 300ml or 1000ml ml plastic bottles with a plastic measuring cup. The graduations on the measuring cup are: 2.5ml, 5ml, 10ml, 15ml, 20ml, 25ml and 30ml.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation holder is:

Mylan IRE Healthcare Limited, Unit 35/36, Grange Parade, Baldoyle Industrial Estate,
Dublin 13.

The manufacturer is:

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

This leaflet was approved in April 2022