Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
  - If you have further question, ask your doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
  - If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Duphalac is and what it is used for
2. Before you take Duphalac
3. How to take Duphalac
4. Possible side effects
5. How to store Duphalac
6. Further information

1. 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)
to produce a soft stool.

Duphalac is used to treat hepatic encephalopathy, also called portal systemic encephalopathy (a liver disease causing difficulty thinking, tremor, decreased level of consciousness including coma)

2. 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).

If you suffer from
- galactosaemia (a sever genetic disorder where you cannot digest galactose)
- blockage in your bowel (apart from normal constipation)
If you are not sure, talk to your doctor or pharmacist before taking Duphalac.

**Take special care with Duphalac**
Please consult your doctor before taking Duphalac if you suffer from any medical conditions or illnesses, in particular:
– if you are unable to digest milk sugar (lactose) 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, 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.

Please do not use Duphalac without medical advice for more than two weeks. 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.

**Taking other medicines**
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

**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.

**Driving and using machines**
Duphalac is unlikely to affect your ability to drive or use machines.

**Pregnancy and breast-feeding**
Talk to your doctor before taking this medicine if you are pregnant, might become pregnant or are breast-feeding.
Ask your doctor or pharmacist for advice before taking any medicine, if you are pregnant or breast-feeding. Duphalac can be used when pregnant or breast-feeding if necessary.

**Important information about some of the ingredients of Duphalac**
Duphalac contains lactulose which may contain small amounts of fructose, galactose, epilactose and lactose (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.

3. HOW TO TAKE DUPHALAC

If this medicine is from your doctor or pharmacist, do exactly as they have told you. Otherwise follow the instructions below. If you do not understand the instructions, or you are not sure, ask your doctor or pharmacist.

Taking this medicine
- Take Duphalac from a spoon or measuring cup.
- You can mix it with fruit juice or water.
- 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.

Dosing in Constipation

The dose may be given once daily, for example during breakfast, or divided into two doses a day; for Duphalac in bottles use the measuring cup.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Starting dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>15 ml twice daily</td>
</tr>
<tr>
<td>Children (5-10 years)</td>
<td>10 ml twice daily</td>
</tr>
<tr>
<td>Children (2-5 years)</td>
<td>5 ml twice daily</td>
</tr>
<tr>
<td>Infants 1-2 years</td>
<td>2.5 ml – 5 ml twice daily</td>
</tr>
<tr>
<td>Infants 1 month – 1 year</td>
<td>2.5 ml twice daily</td>
</tr>
</tbody>
</table>

Dosing in Hepatic Encephalopathy

Initially 30 to 50 ml three times daily; dosage should be subsequently adjusted to produce 2 to 3 soft stools daily.

Use in Children

Use of laxatives in children and infants should be exceptional and under medical supervision because it can disturb the normal reflexes for passing stools. Please do not give Duphalac to children (< 14 years) before consulting your doctor for prescription and careful supervision.

If you take more Duphalac than you should

In case of overdosage, you may experience diarrhoea and abdominal pain. Contact your doctor or pharmacy if you have taken more Duphalac than you should.
If you forget to take Duphalac
If you forget to take 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 have any further questions on the use of this product, ask your doctor or pharmacist.

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 this medicine:

- Flatulence (wind), especially during the first few days of treatment. This usually disappears after a few days.
- Nausea (feeling sick)
- Vomiting
- When a higher dose than recommended is used, you may experience abdominal pain and diarrhoea.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE DUPHALAC

- Keep out of the reach and sight of children.
- Do not use Duphalac 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.

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. FURTHER INFORMATION

What Duphalac contains
- The active substance is lactulose. 5 ml of Duphalac contains 3.335 g 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 oral solution is a clear, colourless to brownish yellow viscous liquid.
• Duphalac oral solution is also available in 300 ml or 1000 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:
Abbott Healthcare Products Limited,
Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, SL6 4XE, UK.
The manufacturer is:
Abbott Biologicals B.V.,
8121 AA, Olst,
The Netherlands.

For further information contact:
Abbott Laboratories Ireland Ltd., 4051 Kingswood Drive, Citywest Business Campus,
Dublin 24.
For information in large print, tape, CD or Braille, phone 01 469 1500

This leaflet was approved in June 2014

Duphalac
3.335g/5ml oral solution
lactulose solution

Follow your doctor’s instructions.
Dosage guide:
Constipation: Starting dose:
Adults 15 ml twice daily
Children, 5-10 years 10 ml twice daily
Children, 2-5 years 5 ml twice daily
Infants, 1-2 years 2.5-5 ml twice daily
Infants, 1 month-1 year 2.5 ml twice daily
Hepatic encephalopathy
(hepatic coma), initially 30-50 ml three times daily.
Subsequently adjust dosage to produce 2 or 3 soft stools each day.
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