

Package leaflet: Information for the patient

Brillphalac 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 or pharmacist 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 your doctor if you do not feel better or if you feel worse after several days.

What is in this leaflet

1. What Brillphalac 3.335 g/5 ml oral solution is and what it is used for
2. What you need to know before you take Brillphalac
3. How to take Brillphalac
4. Possible side effects
5. How to store Brillphalac
6. Contents of the pack and other information

1. What Brillphalac 3.335 g/5 ml oral solution is and what it is used for

This medicine 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.

Brillphalac 3.335 g/5 ml oral solution is used to treat constipation (infrequent bowel movements, hard and dry stools).

Brillphalac 3.335 g/5 ml oral solution is also used to treat hepatic encephalopathy (a liver disease causing confusion, tremor, decreased level of consciousness including coma). Hepatic encephalopathy can lead to a hepatic coma.

2. What you need to know before you take Brillphalac

Do not take Brillphalac if:

- You are allergic (hypersensitive) to lactulose or any of the other ingredients of this medicine (listed in section 6)

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

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Brillphalac 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 this medicine if you suffer from:

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

The usual dose of Brillphalac in constipation is unlikely to affect diabetics. If you have diabetes and are treated for hepatic encephalopathy, your dose of Brillphalac 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 electrolytes 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 Brillphalac.

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

If you take this medicine 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 Brillphalac for longer without medical advice.

Children

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

Other medicines and Brillphalac

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

Brillphalac with food, drink and alcohol

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

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

This medicine can be used during pregnancy and when breast-feeding if necessary.

No effects on fertility are to be expected.

Driving and using machines

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

Important information regarding the ingredients of this medicine

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

3. How to take Brillphalac

Always take this medicine exactly described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Taking Brillphalac

- Take this medicine 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 this medicine is taken for long periods.
- This medicine 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 starting dose is 15-45ml per day. After this dose can be adjusted to 15-30ml daily.

Children 7 to 14 years: The starting dose is 15ml. After this the dose can be adjusted to 10-15ml.

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 this medicine to children (under 14 years) before consulting your doctor for prescription and careful supervision.

Hepatic encephalopathy (adults only)

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: 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 impairment: No special dosage recommendations exist.

If you take more of Brillphalac than you should

If you take more of this medicine than you should stop taking Brillphalac and talk to a doctor or pharmacist straight away.

You may have diarrhoea, loss of electrolytes and abdominal pain.

If you forget to take Brillphalac

If you forget to take a dose do not worry, just take your next dose at the usual time.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Brillphalac

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 to 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 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 your doctor, pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the 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 Brillphalac

- Keep this medicine out of the sight and reach of children.
- Store below 25°C. Use within 12 months of first opening
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Brillphalac contains

- The active substance is lactulose. Each 5 ml of oral solution contains 3.335 g of lactulose.
- This medicine does not contain any other ingredients. However, it may contain small amounts of other sugars, such as lactose, galactose, epilactose, tagatose and fructose.

What Brillphalac looks like and contents of the pack

- This medicine is clear, viscous liquid, colourless or pale brownish yellow.
- This medicine is available in bottles of 300ml, 500ml. A measuring cup with filling marks is supplied with each container.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

Brillpharma (Ireland) Limited
Inniscarra, Main Street,
Rathcoole, Co. Dublin
Ireland
E-mail: info@brillpharma.co.uk

Manufacturer:

Pharmadan A/S,
Sognevej 92
DK-9620 Aalestrup,
Denmark

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