

Duphalac®

667 mg/ml, oral solution
667 mg/ml lactulose

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 questions, please ask your doctor or pharmacist. This medicine has been prescribed to you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Duphalac is a clear, viscous, colourless to brownish yellow aqueous solution (liquid) for oral administration containing 667 g lactulose per 1000 ml.

Duphalac oral solution does not contain any excipients, but may contain small amounts of related sugars (e.g. lactose, galactose, epilactose, fructose) derived from the route of synthesis.

Indications

- Constipation: regulation of the colonic physiological rhythm
- When soft stool is considered of medical benefit (haemorrhoids, post colonic/anal surgery)
- Hepatic encephalopathy (HE): treatment and prevention of hepatic coma or precoma

Dosage and administration

Always take Duphalac oral solution exactly as your doctor has told you. If you have any questions, you should check with your doctor or pharmacist.

You may take Duphalac oral solution diluted or undiluted. Take your dose of lactulose in one swallow; do not hold the solution in your mouth for any length of time.

Your doctor will adjust the dosage according to your response to the medicine. If you have been prescribed a single daily dose, always take it at the same time of day, e.g. during breakfast.

During therapy with laxatives it is important for you to drink sufficient amounts of fluids (1.5 – 2 litres, equal to 6-8 glasses) during the day.

Dosing in constipation or where soft stool is considered of medical benefit:

Duphalac may be taken as a single daily dose or in two divided doses. Your doctor will tell you which frequency to use.

For Duphalac in a bottle, use the measuring cup may be used.

Based upon treatment response your doctor may adjust the starting dose to the maintenance dose after a few days. Several (2-3) days of treatment may be needed before treatment effect occurs

	Duphalac oral solution	
	Starting dose daily	Maintenance dose daily
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

Dosing in HE (for adults only):

Starting dose: 3 to 4 times daily 30-45 ml

The dose should be adjusted by your doctor to the maintenance dose to achieve 2 to 3 soft stools per day

Paediatric population

The safety and efficacy in children (new born to 18 years of age) with HE have not been established. No data are available.

Elderly patients and patients with renal or hepatic insufficiency. No special dosage recommendations exist, since systemic exposure to lactulose is negligible.

Contraindications

Do not take Duphalac oral solution

- If you are hypersensitive (allergic) to lactose or to any of the ingredients of Duphalac oral solution
- If you suffer from galactosaemia
- If you suffer from gastrointestinal obstruction, digestive perforation or risk of digestive perforation.

Warnings and special precautions for use

Consultation of a physician is advised in case of:

- Painful abdominal symptoms of undetermined cause before the treatment is started.
- Insufficient therapeutic effect after several days.

If the desired results are not observed after several days of treatment, consult your doctor. Patients who are intolerant to lactose should take Duphalac oral solution with care (because it contains lactose, see section **Important information about the ingredients**).

The dose normally used in constipation should not pose a problem for diabetics. However, the dose used in the treatment of HE is usually much higher and should be taken into consideration for diabetics.

Chronic use of unadjusted doses and misuse can lead to diarrhoea and disturbance of the electrolyte balance.

Paediatric population

Use of laxatives in children should be exceptional and under medical supervision. It should be taken into account that the defaecation reflex could be disturbed during the treatment.

You may want to take protective measures, such as using diapers, for your small child.

This product contains lactose, galactose and small amounts of fructose. Therefore, patients with the rare hereditary problems of galactose or fructose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Interactions

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

No interaction studies with other medications have been performed

Pregnancy and lactation

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

Pregnancy

During pregnancy, no effects to the fetus are anticipated, since systemic exposure of lactulose to the pregnant woman is negligible.

Duphalac can be used during pregnancy

Lactation

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of lactulose to the breast-feeding woman is negligible.

Duphalac oral solution can be used during breastfeeding

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