



Read the package leaflet before use.
 Oral solution contains lactulose.
 For oral use.
 Do not store above 25°C.
 Store in the original package.
 Keep this medicine out of the reach
 and sight of children.



RF6581



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.

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Duphalac is a clear, viscous liquid, colourless to brownish yellow aqueous solution for oral administration containing 667 g lactulose

Duphalac oral solution does not contain any excipients, but may contain small amounts of related sugars (e.g. lactose, galactose, epilactose) 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)
- Portal systemic encephalopathy (PSE): 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. You may take lactulose as a single daily dose or in two divided doses, using the measuring cup.

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 to your individual needs.

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If you have been prescribed a single daily dose, always take it at the same time of day, e.g. during breakfast.

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

	Duphalac oral solution	
	Starting dose	Maintenance dose
Adults	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
Babies	5 ml	5 ml

Dosing in precoma and coma hepaticum (for adults only):

Starting dose: 20 - 30 g (2 - 3 sachets) or 30 - 45 ml, three to four times daily

The maintenance dose should be adjusted so that soft stools are produced 2 - 3 times per day.

Contraindications

Do not take Duphalac oral solution

- If you are hypersensitive (allergic) to lactulose or to any of the excipients of Duphalac oral solution
- if you suffer from galactosaemia

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- if you suffer from bowel obstruction

Warnings and special precautions for use

If the desired results are not observed after several days of treatment, consult your doctor. Patients who are intolerant to lactulose should

take oral solution with care because it contains lactulose (see

“Important information about the ingredients”). The dose normally used in constipation should not pose a problem for diabetics. The dose used in the treatment of (pre)coma hepaticum is usually much

higher and should be taken into consideration for diabetics.

Laxatives (of any kind) should be used only when absolutely necessary and only after consulting a doctor. Faecal retention abilities could be disturbed during treatment with Duphalac oral solution. You may want to take protective measures, such as using

diapers, for your small child.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Interactions

No interaction studies with other medications have been performed.

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

prescription.

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Pregnancy and lactation

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

There is only limited data on pregnant patients taking this medicine. The available data indicates neither malformative nor foeto/neonatal

toxicity to the foetus or the newborn child).

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.

The use of Duphalac oral solution may be considered during pregnancy and lactation if necessary.

Effects on ability to drive and use machines

Duphalac oral solution has no or negligible influence on the ability to drive and use machines.

Important information about the ingredients

Duphalac oral solution contains lactulose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, especially lactulose, contact your doctor before taking this medicinal product.

Undesirable effects

Like all medicines, Duphalac oral solution may cause side effects, although not everyone experiences them.

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If you notice any side effects not mentioned in this leaflet, or if any of the side effects gets serious, please inform your doctor or pharmacist.

Flatulence may occur during the first few days of treatment. As a rule,

it subsides after a couple of days. Diarrhoea and abdominal pain

may be experienced if you take a higher dose than instructed. If this

occurs, the dosage should be decreased to reflect the recommended

dosage.

If you are taking a high dose (normally only used for portosystemic encephalopathy, PSE) for an extended period of time, you may experience an electrolyte imbalance (not enough electrolytes in your blood) due to diarrhoea.

Gastrointestinal disorders

Flatulence, abdominal pain, nausea and/or vomiting may be experienced.

If taken in too high a dose, diarrhoea may also occur.

Investigations

Electrolyte imbalance (not enough electrolytes in your blood) due to

diarrhoea may occur.

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Overdose

If you have taken too high a dose you may observe the following

symptoms: diarrhoea and/or abdominal pain.

Under these circumstances, the treatment should be stopped or the

dosage reduced sufficiently for the symptoms to subside.

Extensive fluid loss by diarrhoea or vomiting may require the

intake of extra electrolytes. Please ask your doctor or pharmacist for

advice.

Pharmacodynamics

Pharmacotherapeutic group: Osmotically acting laxatives

The following is a detailed description of how Duphalac oral solution works. If you would like an explanation or further information regarding this information, please consult your doctor.

Information for the doctor:

In the colon lactulose is broken down by colonic bacteria into low-molecular organic acids. These acids lead to a lowering of pH in the colonic lumen and via an osmotic effect to an increase of the volume of the colonic contents. These effects stimulate the peristalsis of the colon and return the consistency of the stools. The constipation is cleared and the physiological rhythm of the colon is reinstated.

In portal systemic encephalopathy (PSE) or (pre)coma hepaticum, the

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effect has been attributed to suppression of proteolytic bacteria by an increase of acidophilic bacteria (e.g. lactobacillus), trapping of ammonia in the ionic form by acidification of the colonic contents, catharsis due to the low pH in the colon as well as an osmotic effect, and alteration of the bacterial nitrogen metabolism by stimulating the bacteria to utilize ammonia for bacterial protein synthesis. Within this context, however, it should be realized that hyperammonia alone cannot explain the neuropsychiatric manifestations of PSE. The ammonia, however, might serve as a model compound for other nitrogenous substances.

Lactulose as a prebiotic substance strengthens the growth of health promoting bacteria, like bifidobacterium and lactobacillus, whereas potentially pathogenic bacteria, like clostridium and Escherichia coli may be suppressed.

This may lead to a more favorable balance of the intestinal flora.

Pharmacokinetics

The following is a detailed description of how Duphalac oral solution is metabolized in the body. If you would like an explanation or further information regarding this information, please consult your doctor.

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- in 5 litre bottles, which are made of HDPE with HDPE closures.
- in 200, 300, 500 and 1000 ml bottles, which are made of HDPE with polypropylene closures and come with a polypropylene measuring cup.

Not all pack sizes may be marketed.

Further information

No special requirements.

The information in this leaflet is limited. For further information, please contact your doctor or pharmacist.

Date of information

November 2008

Manufactured by

Abbott Biologicals B.V.,
The Netherlands

for

Abbott Healthcare Products B.V.,
The Netherlands

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Information for the doctor:

Lactulose is poorly absorbed after oral administration. Not being absorbed as such it reaches the colon unchanged, where it is metabolised by the colonic bacterial flora. Metabolism is complete at doses up to 25 - 50 g or 40 - 75 ml; at higher dosages, a proportion may be excreted unchanged.

Incompatibilities

Not applicable.

Storage conditions

Do not store above 25°C.

Store in the original package.

Do not use this medicine after the expiry date stated on the carton and sachet or bottle.

Keep this medicine out of the reach and sight of children.

Pack sizes

Duphalac oral solution comes in

- 10 or 20 sachets per pack with 15 ml per sachet. The sachets are made of a polyester/ aluminium/polyethylene laminate.

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THIS MEDICATION

is a product which affects your health and its use contrary to instructions is dangerous to you.

Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold you the medication.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not interrupt the period of treatment prescribed.
- Do not repeat the same prescription without first consulting your doctor.
- Keep all medications out of reach of children.

Council of Arab Health Ministers,
Union of Arab Pharmacists

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