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 solution (liquid) for oral administration containing 66.7 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.

Composition:
100 ml Duphalac contains: 66.7 g lactulose U.S.P.

Indications:
- Constipation: regulation of the colon 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.

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

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

In the colon lactulose is broken down by colonic bacteria

Summary of the safety profile
The safety and efficacy in children (newborns to 18 years of age) with HE have not been established.

For Administration of this product to children under 1 year of age) with HE have not been established.

Very common Common Uncommon Rare

Gastrointestinal disorders
Diarrhoea
Flatulence, abdominal pain, nausea, vomiting

Investigations
Electrolyte disorders abdominal pain

Pancreatic population
The safety profile in children is expected to be similar as in adults.

Contraindications
Hypersensitivity to the active substance or to any of the ingredients.

Interactions with other medicinal products and other forms of interaction
No interaction studies have been performed.

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

Painful abdominal symptoms of undetermined cause

If the dose is too high, the following may occur:
- Flatulence may occur during the first few days of treatment.
- If high doses (not normally associated with Hepatic encephalopathy; HE) are used for an extended period of time, the patient may experience an electrolyte imbalance due to diarrrhea.

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

Tabled list of adverse reactions
The following undesirable effects have been experienced with the below indicated frequencies in lactulose-treated patients in placebo-controlled clinical trials [very common (≥ 1/10); common (≥ 1/100 to <1/10); uncommon (≥ 1/10,000 to <1/1000); rare (≥ 1/100,000 to <1/10,000); very rare (<1/100,000)]

- Painful abdominal symptoms of undetermined cause before the treatment is started
- Insufficient therapeutic effect after several days. Lactulose should be administered with care to patients who are intolerant to lactose (see ‘List of patients?’)
- The dose normally used in constipation should not pose a problem for diabetics. The dose used in the treatment of HE is usually much higher and may need to be taken into consideration for diabetics.
- Chronic use of undulated dosages and mixes can lead to diarrrhea and disturbance of the electrolyte balance.
- The product contains lactose, galactose and small amounts of fructose. Therefore, patients with the rare hereditary problem of galactose or fructose intolerance, the Lapp lactose deficiency or glucosegalactose malabsorption should not take this medicine.
- Constipation, abdominal distention, flatulence

Flatulence may occur during the first few days of administration. Under medical supervision.

Under these circumstances, the treatment should be stopped or the dosage reduced sufficiently for the symptoms to subside.

Painful abdominal symptoms of undetermined cause before the treatment is started

Constipation, abdominal distention, flatulence

Extensive fluid loss by diarrhoea or vomiting may require the intake of extra electrolytes.

If the dose is too high, the following may occur:
- Flatulence may occur during the first few days of treatment.
- If high doses (not normally associated with Hepatic encephalopathy; HE) are used for an extended period of time, the patient may experience an electrolyte imbalance due to diarrrhea.

Incompatibilities
Not applicable.

Presentation
1. Bottle of 300 ml - W153
2. Bottles of 240 ml - W153

To be sold on the prescription of a registered medical practitioner only.

Keep all medicines out of the reach of children.

Not to be injected.

Manufactured by:
Canilis Group
Abbott Products Inc., Canada

Packaged by:
Higginson Laboratories Ltd., 175 S.M. Mallin Road, Lahore.
Marked by:
Abbott Laboratories (Pakistan) Ltd., Landhi, Karachi.

Under Licence from Abbott Healthcare Products B.V., Weesp, Holland

Abbott Healthcare Products B.V.

Duphalac PIL
Size: 18.6 cm x 10 cm
Process Black

08-07-2015
Imran, Abbott