

SCHEDULING STATUS

S0

PROPRIETARY NAME (AND DOSAGE FORM)

DUPHALAC

Syrup

COMPOSITION

5 ml Duphalac contains lactulose (4-0-b-D-galactopyranosyl-D-fructofuranose) 3,3 g.

PHARMACOLOGICAL CLASSIFICATION

A. 11.5 Laxatives.

PHARMACOLOGICAL ACTION

Duphalac is a synthetic disaccharide of fructose and galactose, which is not split into its monosaccharide constituents in the small intestine due to the lack of a specific enzyme. It reaches the colon unchanged where it is broken down by the saccharolytic flora into organic acids, such as lactic acid and acetic acid, acids formed in the colon under physiological conditions. Due to this local osmotic effect in the colon, water is retained, the faecal mass softened and normal colonic peristalsis restored. The mode of action differs from that of conventional laxatives.

In portal systemic encephalopathy administration of large doses of Duphalac results in a significant reduction in the pH of the colonic contents. Lowering the pH promotes conversion of non-ionised ammonia into ionised form. The latter form being non-absorbable leads to reduction of absorption of ammonia from the intestine into the portal circulation and may even promote the excretion of ammonia from the circulation into the faeces.

In addition, the enhanced growth of saccharolytic bacteria results in a decreased formation of ammonia.

Duphalac cannot be hydrolysed in the intestine, thus very little absorption occurs. Small amounts of nonhydrolysed lactulose may be absorbed, but these are readily excreted via the kidneys.

INDICATIONS

Constipation

Particularly when associated with laxative habituation or for those patients in whom constipation presents a special problem, eg children, obstetric and post-surgical patients.

Portal systemic encephalopathy

Hepatic coma or precoma stages where hyperammonaemia is present.

CONTRA-INDICATIONS

Galactosaemia.

DOSAGE AND DIRECTIONS FOR USE

Constipation

Dosage can vary widely with the severity of the condition. A relatively large initial dose should be followed by a smaller maintenance dose after the first three days of treatment. Only one dose daily needs to be taken, preferably after breakfast.

Recommended dosages are as follows:

Usual starting dose

Adults: 30 ml (6 x 5 ml spoonfuls).
Children (6-14 years): 15 ml (3 x 5 ml spoonfuls).
Children (1-5 years): 10 ml (2 x 5 ml spoonfuls).
Infants: 5 ml (1 x 5 ml spoonful).

Maintenance dose

Adults: 15-30 ml (3-6 x 5 ml spoonfuls).
Children (6-14 years): 10-15 ml (2-3 x 5 ml spoonfuls).
Children (1-5 years): 5-10 ml (1-2 x 5 ml spoonfuls).
Infants: 2,5-5 ml (½-1 x 5 ml spoonful).

Portal systemic encephalopathy

Initial dose of 30-50 ml 3 times daily. Subsequently adjust the dose to produce two or three soft stools daily.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

Although occasionally nausea and meteorism or flatulence have been reported on the high initial dosages used, these effects normally disappear when the maintenance dosage has been reached. As lactulose is not absorbed to any significant degree, it may be given to diabetics. Note should, however, be taken that Duphalac contains small amounts of lactose and galactose.

Applicant/PHCR: Abbott Laboratories S.A. (Pty) Ltd
Product Proprietary Name: DUPHALAC

Dosage Form and strength: 3.3g/5ml syrup

Diarrhoea indicates overdosage.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

See "Side effects and special precautions".

IDENTIFICATION

Clear, pale yellow, sweet-tasting syrup.

PRESENTATION

150 ml, 500 ml, 2,5 l and 5 l bottles.

Boxes of either 6, 10, 20 or 30 sachets containing 15 ml Duphalac.

STORAGE INSTRUCTIONS

Store at temperatures not exceeding 25°C. Keep out of reach of children.

REGISTRATION NUMBER

K/11.5/180

NAME AND BUSINESS ADDRESS OF THE APPLICANT

Abbott Laboratories S.A. (Pty) Ltd
Abbot Place
219 Golf Club Terrace
Constantia Kloof
1709

DATE OF PUBLICATION OF THIS PACKAGE INSERT

25 September 1979