APPROVED PACKAGE INSERT

SCHEDULING STATUS S0

PROPRIETARY NAME (and dosage form):

DUPHALAC DRY (Crystalline powder)

COMPOSITION
10 g of DUPHALAC Dry contains 10 g **lactulose** (4-0-beta-D-galactopyranosyl-D-fructofuranose) (a maximum of 0,25 g galactose and 0,2 g lactose).

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 lactulose 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.
Lactulose 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
a) 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.

b) Portal systemic encephalopathy:

Hepatic coma or pre-coma stages where hyperammonaemia is present.

CONTRA-INDICATIONS
Galactosaemia, including patients on a galactose-free diet. Patients with intestinal obstruction.

DOSAGE AND DIRECTIONS FOR USE

a) Constipation:

The dosage for constipation can be varied according to the individual response, but the following serves as a guide.

	Starting dose (3 days) gram per day	Maintenance dose gram per day
Adults	10-30 g	10-20 g
Children 7-14 years	10 g	10 g
Children 1-6 years	5-10 g	5-10 g

If there is no response within 48 hours the dosage can be increased and if diarrhoea occurs the dosage should be decreased.

Since DUPHALAC Dry exerts its effect when it reaches the colon it may take 1-2 days before normal defaecation occurs.

b) Portal systemic encephalopathy:

Starting dose 20-35 g three times a day.

Maintenance dose has to be adjusted to the individual response.

DUPHALAC Dry can be best taken with breakfast cereals, or drinks such as tea, coffee, fruit juice or milk.

SIDE EFFECTS AND SPECIAL PRECAUTIONS
Duphalac may cause abdominal discomfort associated with flatulence or cramps. Nausea and vomiting have been reported less frequently following high doses. Care should be taken in patients with lactose intolerance and in diabetic patients because of the presence of galactose and lactose.
Prolonged use or overdosage may result in diarrhoea with excessive loss of water and electrolytes, particularly potassium.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
See "Side effects and special precautions". Treatment is symptomatic and supportive.

IDENTIFICATION
A white to slightly yellow-coloured crystalline powder.

PRESENTATION
Packs of 10 or 30 sachets of 10 g lactulose.

STORAGE INSTRUCTIONS
Store below 25°C. Keep out of reach of children.

REGISTRATION NUMBER
28/11.5/0427

NAME AND BUSINESS ADDRESS OF THE APPLICANT
Abbott Laboratories S.A. (Pty) Ltd
Abbott Place
219 Golf Club Terrace
Constantia Kloof
1709

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