EVAC

Lactulose Solution USP

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains: Lactulose 3.35g (as Lactulose concentrate USP).

PHARMACEUTICAL FORM

Yellow coloured solution.

CLINICAL PARTICULARS

Indications a)Constipation: Particularly when associated with laxative habituation or for those patients in whom constipation presents a special problem, e.g. children, obstetric and post-surgical patients.b)Portal systemic encephalopathy: Hepatic coma or precoma stages where hyperammonaemia is present.

Posology and method of administration

a) 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 spoonful)
Children (6-14 years) : 15 ml (3 x 5 ml spoonful)
Children (1-5 years) : 10 ml (2 x 5 ml spoonful)
Infants : 5 ml (1 x 5 ml spoonful)

Maintenance dose:

Adults : 15-30 ml (3-6 x 5 ml spoonful)
Children (6-14 years) : 10-15 ml (2-3 x 5 ml spoonful)
Children (1-5 years) : 5-10 ml (1-2 x 5 ml spoonful)
Infants : 2.5-5 ml (½-1 x 5 ml spoonful).

b) Portal systemic encephalopathy

Initial dose of 30 – 50 mL three times daily. Subsequently adjust the dose to produce two or three soft stools daily.

Contraindications

Galactosaemia, including patients on a galactose-free diet, and in patients with intestinal obstruction.

Chronic Portal Hypertension and Hepatic Encephalopathy:

The usual maintenance dose is 30 to 45 ml (6 to 9 medicine measures) three or four times daily; this is adjusted such that there are two or three soft stools daily and a faecal pH of 5 to 5,5. Therapy can be initiated with hourly doses of 30 to 45 ml (6 to 9 medicine measures) if indicated. Maintenance of the proper pH is essential for appropriate effects on intestinal elimination of ammonia.

Side-effects and special precautions:

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

For management of chronic portal hypertension and encephalopathy other laxatives should not be employed concurrently in order to avoid inadequate acidification of the stool.

Known symptoms of overdosage and particulars of its treatment:

See "Side-effects and special precautions". Treatment is symptomatic.

Warnings:

This medicine should not be used in the presence of abdominal pain, nausea or vomiting. Frequent or prolonged use of this preparation may result in dependence on laxatives and loss of normal bowel function. If you have noticed sudden change in bowel habits that persist over a period of greater than 2 weeks, consult a doctor before using the laxative. If the recommended use of this product for 1 week has had no effect, discontinue use and consult a doctor. Rectal bleeding or failure to have a bowel movement after use of a laxative may indicate a serious condition. Discontinue use and consult a doctor. Drink a full glass of liquid with each dose to prevent dehydration.

PHARMACOLOGICAL PROPERTIES

Pharmacological classification:

Laxatives.

Pharmacological action:

Lactulose is a synthetic disaccharide derivative of lactulose and acts by its osmotic properties in the luminal fluid. The primary osmotic effect of lactulose, which is not absorbed in the upper intestine, may be augmented in the distal ileum and colon by bacterial metabolism of the disaccharide to lactate and other organic acids that are only partially absorbed. There is speculation that the concomitant reduction of luminal pH enhances motility and secretion. The increased osmotic activity in the lumen that follows administration of lactulose results in modest accumulation of fluid and passage of soft, formed faeces in 1 to 3 days. Another important aspect of the action of lactulose is reduction of intestinal absorption of ammonia, presumably because of reduced production and increased utilization of ammonia by intestinal bacteria and enhanced excretion of ammonia in the faeces.

Pharmacokinetic properties

Following oral administration, a negligible amount of Lactulose is absorbed in the gastro-intestinal tract. It passes essentially unchanged into the large intestine where it is metabolized by saccharolytic bacteria, forming simple organic acids such as lactic and acetic acid. Urinary excretion has been reported to be 3% or less.

CATEGORY: Prescription Only Medicine (POM).

STORAGE CONDITION: Store in a dry place at temperature not exceeding 30°C. Keep out of reach of children. Do not refrigerate.

SHELF LIFE: As per the product label.

PRESENTATION: Amber coloured bottle of 100 ml

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LICENCE HOLDER: LABORATORY & ALLIED LTD.

Laboratory & Allied Ltd.
Plot No. 209/10349, Mombasa Road,
P.O. Box 42875, Nairobi, Kenya

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