

Tulac®

Lactulose oral solution

DESCRIPTION

Tulac® is an oral solution of lactulose. The active principle of **Tulac®** oral solution, lactulose, is neither broken down nor absorbed in the stomach and small intestine. In the colon it acts as a substrate for and promotes the growth of naturally occurring glycolytic micro-organisms and is broken down to lactic acid. As a result water content in the colon increases and helps to prevent constipation. The pH of the intestinal contents is lowered, the growth of acidophilic flora is promoted and the putrefactive micro-organisms are suppressed. This reduces the formation of ammonia and amines and their absorption from the gut, thus leading to a fall in blood ammonia levels (responsible for hepatic encephalopathy). By normalising the intestinal flora **Tulac®** oral solution ensures the passage of normal stools, without excessive peristalsis.

INDICATIONS

- Chronic constipation
- Chronic portal systemic encephalopathy

DOSAGE AND ADMINISTRATION

Adults

Initially: 15-30 ml daily for first 2-3 days (45 ml may be given in obstinate cases).

Maintenance: 10-15 ml daily or according to the need of the patient.

Children

Initially: 10-25 ml daily for first 2-3 days.

Maintenance: 5-15 ml daily or according to the need of the patient.

Dosage does not appear to be related to the age or weight of the child and should be adjusted to produce the required response.

Chronic portal systemic encephalopathy

Initially 30-50 ml three times daily according to the requirements of the patient for adequate acidification of the colonic contents.

Use in the elderly

No evidence exists that elderly patients require different dosages or show different side-effects from younger patients.

CONTRAINDICATIONS

In common with other preparations used for the treatment of constipation, **Tulac®** oral solution should not be used in patients with gastrointestinal obstruction. **Tulac®** oral solution should not be given to patients with galactosaemia or lactose intolerance.

SIDE EFFECTS

Side-effects rarely occur after the administration of lactulose oral solution. Mild transient effects such as abdominal distension or cramps and flatulence, which subside after the initial stages of treatment, have occasionally been reported. High doses may provoke nausea in some patients.

This can be minimised by administration with water, fruit juice or with meals.

PRECAUTIONS

Lactulose is for oral consumption only. It is not for injection. Prolonged use in children may contribute to the development of dental caries.

PREGNANCY AND LACTATION

Lactulose oral solution should be used with caution during the first trimester of pregnancy.

PHARMACEUTICAL PRECAUTION

Store in a dry place. Keep out of reach of children.

PACKAGING

Tulac® 50 ml OS : Amber PET bottle containing 50 ml oral solution. Each 15 ml contains lactulose BP 10 g.

Tulac® 100 ml OS : Amber PET bottle containing 100 ml oral solution. Each 15 ml contains lactulose BP 10 g.

Tulac® 200 ml OS : Amber glass bottle containing 200 ml oral solution. Each 15 ml contains lactulose BP 10 g.

SK-F

Manufactured by
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