Osmolax®

Lactulose USP

COMPOSITION

Osmolax® solution : Each 5 ml concentrated oral solution contains Lactulose USP 3.35 gm.

PHARMACOLOGY

Lactulose is a disaccharide, which is not hydrolyzed in the small intestine. Therefore it can not be absorbed and is transported to the colon with water to retain the osmotic balance. It provides a natural substrate for the saccharolytic bacterial flora in the colon. In the colon, several species of bacteria can hydrolyze Lactulose to the monosaccharides galactose and fructose. By encouraging this normal metabolic activity of the bacteria, the osmotic pressure of the colonic contents is doubled and more water is drawn into the bowel. Further metabolism of the monosaccharides leads to the production of acetic acids and the subsequent lowering of colonic pH. This acidification of the colonic contents is considered to be the main reason for the effectiveness of Lactulose solution. In chronic portal systemic encephalopathy it may be associated with the decrease in the relative concentration of free ammonia, the major agent involved in the cerebral disturbance.

INDICATION

1. Constipation
2. Hepatic encephalopathy (Portal systemic encephalopathy): hepatic coma

DOSAGE AND ADMINISTRATION

Constipation: Initially **Osmolax®** solution may be given twice daily. In due course the dose should be adjusted according to the needs of the individual, but the following serves as a guideStarting dose:
Adults: (including the elderly): 15 ml twice daily.
Children: 5 to 10 years: 10 ml twice daily.
Children under 5 years: 5 ml twice daily.
Babies under 1 year: 2.5 ml twice daily. Osmolax® solution may, if necessary, be taken with water or fruit juice, etc.
Hepatic encephalopathy:
Adults (including the elderly):
Initially 30-50 ml three times a day. Subsequently adjust the dose to produce two or three soft stools each day. Children: No dosage recommended for this indication. Because of Lactulose's physiological mode of action it may take up to 48 hours before effects are obtained. However, clinical experience has shown that this medicament does exhibit a 'carry-over' effect, which may enable
the patient to reduce the dose gradually over a period of time. A maintenance dose of 15 ml per day provides only 14 kilocalories and is
therefore, unlikely to adversely affect diabetic patients.

CONTRAINDICATION AND PRECAUTION

Galactosaemia. In common with other preparations used for the treatment of constipation, Lactulose should not be used when there is evidence of gastro-intestinal obstruction.
Lactose intolerance.

SIDE EFFECT

During the first few days of treatment, meteorism and increased flatulence may occur. These symptoms usually disappear under continued therapy. Diarrhoea may occur especially when used higher dosages, e.g. during treatment of portal systemic encephalopathy. Dosage should then be adjusted to obtain two or three formed stools per day.

USE IN PREGNANCY

Wide clinical experience, together with data from animal reproduction studies has not revealed any increase in embryotoxic hazard to the foetus if used in the recommended dosage during pregnancy. If laxative therapy is needed in pregnancy, use of this drug is acceptable.

STORAGE CONDITION

Store below 30°C. Protect fron light. Do not freeze. Dilution and subsequent storage is not recommended.

HOW SUPPLIED

Osmolax® 100 ml: Box containing 100 ml concentrated oral solution in PET bottle
Osmolax® 200 ml: Box containing 200 ml concentrated oral solution in PET bottle

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH