SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Osmolax Solution

2. Qualitative and quantitative composition

Each 5 ml Concentrated solution contains Lactulose USP 3.35 gm.

For a full list of excipients, see section 6.1

3. Pharmaceutical form

Solution.
A clear, colorless to brownish yellow, flavored viscous liquid, filled and sealed in amber colored PET bottle with SQUARE printed and white colored cap.

4. Clinical particulars

4.1 Therapeutic indications

Constipation
Hepatic encephalopathy (Portal systemic encephalopathy): hepatic coma

4.2 Posology and method of administration

Posology

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 guide-

Starting 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.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

A theoretical hazard may exist for patients being treated with Lactulose solution who may be required to undergo electrocautery procedures during proctoscopy or colonoscopy. Accumulation of H2 gas in significant concentration in the presence of an electrical spark may result in an explosive reaction. Although this complication has not been reported with Lactulose, patients on Lactulose therapy undergoing such procedures should have a thorough bowel cleansing with a non-fermentable solution. Insufflation of CO2 as an additional safeguard may be pursued but is considered to be a redundant measure.

Since Lactulose solution contains galactose (less than 1.6 g/15 mL) and lactose (less than 1.2 g/15 mL), it should be used with caution in diabetics.

In the overall management of portal-systemic encephalopathy it should be recognized that there is serious underlying liver disease with complications such as electrolyte disturbance (e.g. hypokalemia) for which other specific therapy may be required. Infants receiving Lactulose may develop hyponatremia and dehydration.

4.5 Interaction with other medicinal products and other forms of interaction

Do not use lactulose and other laxatives concurrently. In theory, the use of some antibacterials (e.g. neomycin) could eliminate the bacteria that convert lactulose to low molecular weight acids that exert an osmotic effect. However, this has not appeared to be a clinical concern since synergy has been reported when lactulose and antibiotics are used concurrently.

4.6 Fertility, pregnancy, and lactation

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.

4.7 Effects on ability to drive and use machines.

Lactulose has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

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.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

If the dose is too high, the following may occur:

Symptom: diarrhoea and abdominal pain.

Treatment: cessation of treatment or dose reduction. Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

No specific antidote. Symptomatic treatment should be given.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Osmotically acting laxatives

ATC code: A 06A D11

Mechanism of action

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.

5.2 Pharmacokinetic properties

Lactulose is poorly absorbed after oral administration and it reaches the colon unchanged. There it is metabolised by the colonic bacterial flora. Metabolism is complete at doses up to 25-50 g or 40-75 ml; at higher dosages, a proportion may be excreted unchanged

5.3 Preclinical safety data

The results of acute, sub-chronic and chronic toxicity studies in various species indicate that the compound has very low toxicity. The effects observed, appear to be more related to the effect of bulk in the gastrointestinal tract than to a more specific toxic activity. In reproduction and teratology experiments in rabbits, rats or mice no adverse effects were found.

6. Pharmaceutical particulars

6.1 List of excipients

Lemon Tetrarome 987317
Orange Tetrarome 987431 Essence

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage:

Store below 30˚C.

Protect from light. Keep out of the reach of children.

6.5 Nature and contents of container

Each bottle contains 100 ml & 200 ml solution (with a measuring cup).

6.6 Special precautions for disposal and other handling:

No special requirements.

7. Marketing authorization holder and manufacturing site addresses

Marketing authorization holder:

SQUARE Pharmaceuticals Ltd. Square Road, Salgaria, Pabna 6600 BANGLADESH

8. Marketing authorization number

H2025/CTD9990/22038

9. Date of first registration

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10. Date of revision of the text:

03/03/2023