

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lactolax

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of solution contains 3.35 g of lactulose.

3 PHARMACEUTICAL FORM

Oral solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

1. In the treatment of hepatic encephalopathy.
2. In the treatment of constipation.

4.2 Posology and method of administration

Hepatic encephalopathy

Adults including the elderly: Initially 30 - 50 ml (6 - 10 x 5 ml spoonfuls) 3 to 4 times daily; dosage should be subsequently adjusted to produce 2 to 3 soft stools daily and an acidic faecal pH.

Constipation:

Adults including the elderly: Initially 15 ml (3 x 5ml spoonfuls) twice daily. Dosage can often be gradually reduced to 10-20 ml a day or every other day.

Children 5 to 10 years 10 ml (2 x 5ml spoonfuls) twice daily

Children under 5 years 5 ml (1 x 5ml spoonful) twice daily

Each dose may, if necessary be taken with water, milk or fruit juices to increase palatability.

4.3 Contraindications

1. Use in patients who require a galactose-free diet
2. Use in patients with evidence of gastrointestinal obstruction.

4.4 Special warnings and special precautions for use

1. In the event of diarrhoea adequate fluid intake should be maintained during treatment, and the dosage reduced to avoid loss of fluid and potassium and exacerbation of encephalopathy.
2. Long term use of this product is inadvisable except under medical supervision.
3. A dose of 30ml provides 116 KJ (28 Kcals), and is unlikely to adversely affect diabetics.
4. Lactolax should be administered with care to patients who are intolerant to lactose. (It contains 0.3g Lactose per 5ml).

4.5 Interaction with other medicinal products and other forms of interaction

The product should not be used with enteric coated mesalazine as the lower stool pH may prevent mesalazine release. The elimination of colonic bacteria by certain broad spectrum antibiotic agents may interfere with the degradation of lactulose and prevent acidification of colonic contents.

4.6 Pregnancy and lactation

The product may be used if considered essential by the physician.

4.7 Effects on ability to drive and use machines

None Known.

4.8 Undesirable effects

This preparation may temporarily give rise to flatulence, cramps and abdominal discomfort.

4.9 Overdose

There have been no reports of accidental overdose. It is expected that diarrhoea and abdominal cramps would be major symptoms.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Lactulose is a synthetic disaccharide analogue of lactose, which is broken down by colonic bacteria to low molecular weight acids. The resulting increase in osmotic pressure increases stool water and faecal softening, and the increase in acidity attracts ammonia from the blood, traps it as ammonium ion and prevents reabsorption.

5.2 Pharmacokinetic properties

Given orally, only small amounts reach the blood. Urinary excretion has been determined to be 3% or less, and this is virtually complete within 24 hours.

Lactulose does not exert its effect until it reaches the colon. Therefore 24 to 48 hours may be required to produce a normal bowel movement.

5.3 Preclinical safety data

Not relevant.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

No other excipients.

6.2 Incompatibilities

None known.

6.3 Shelf Life

2 years from the date of manufacture.

6.4 Special precautions for storage

Do not store above 25°C and protect from light.

Do not refrigerate.

6.5 Nature and contents of container

Amber glass bottles with screw caps of 150 ml, 300 ml and 500 ml.

Plastic bottles with screw caps of 1000ml and 5000 ml.

6.6 Instructions for use and handling

No special instructions.

7 MARKETING AUTHORISATION HOLDER

Olinka (UK) Ltd.
38/40 Chamberlayne Road,
London, NW10 3JN,
England.

8 MARKETING AUTHORISATION NUMBER

PA 476/9/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th October 1991

Date of last renewal: 11th October 2001

10 DATE OF REVISION OF THE TEXT

October 2001