

IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA0997/008/001

Case No: 2036757

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Intrapharm Laboratories Limited

60 Boughton Lane, Maidstone, Kent ME15 9QS, United Kingdom

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Lactugal 3.4 g/5ml Oral Solution

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **08/06/2007** until **16/10/2010**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lactugal 3.4g/5ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of solution contains 3.4g lactulose.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution

A yellow, banana-flavoured solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the treatment of hepatic encephalopathy and constipation.

4.2 Posology and method of administration

For oral administration.

Hepatic Encephalopathy

Adults:

Initially 30-50ml three to four times daily; dosage should be subsequently adjusted to produce 2-3 soft stools daily and an acidic faecal pH.

Constipation

Adults:

Initially 15ml twice daily. Dosage can often be gradually reduced to 10-20ml a day or every other day.

Children:

5 – 10 years: 10ml twice daily.
1 – 4 years: 5ml twice daily.

4.3 Contraindications

Contra-indicated in patients who require a galactose-free diet and in patients with evidence of gastro-intestinal obstruction.

4.4 Special warnings and 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 with exacerbation of encephalopathy.

2. Long term use of this product is inadvisable except under medical supervision.
3. A dose of 30ml provides 116K.J. (28 kcals), and is unlikely to adversely affect diabetics.
4. Lactugal should be administered with care to patients who are intolerant of lactose.
(It contains 0.3g of lactose per 5ml).

4.5 Interaction with other medicinal products and other forms of interaction

The elimination of colonic bacteria by certain broad spectrum antibiotics may interfere with the degradation of lactulose and prevent acidification of colonic contents.

4.6 Pregnancy and lactation

Safe use during pregnancy has not been established. The product should be used only if considered essential by the physician.

4.7 Effects on ability to drive and use machines

There is no evidence to show that lactulose affects driving ability.

4.8 Undesirable effects

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

4.9 Overdose

If clinically important electrolyte disturbances occur, suitable corrective measures should be taken.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Lactulose is a synthetic disaccharide which is metabolised by gastro-intestinal bacterial flora to low molecular weight acids (chiefly lactic and acetic acids). There is no endogenous metabolising enzyme in the human gut.

Its mode of action in constipation is as an osmotic agent producing soft stools.

A dual mode of action is proposed for the efficacy of lactulose in Portal System Encephalopathy, relating to the metabolism of ammonia and subsequent nitrogenous toxins. The reduction in gastro-intestinal pH results in a net entrapment of ammonia in the gut lumen. Lactulose has also been shown to alter ammonia metabolism by microbial flora.

5.2 Pharmacokinetic properties

Lactulose is absorbed from the gastro-intestinal tract to 0.4 - 2% and is excreted unchanged with the urine. There are no human lactulose disaccharase enzymes; metabolism of lactulose to lactic acid occurs via gastro-intestinal microbial flora only. Due to its poor bioavailability, plasma lactulose concentrations are negligible.

There are no known changes in kinetic properties in patients with organic diseases which may alter drug disposition.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Banana Flavoured Powder (17.41.0042)
Quinoline yellow (E104)
Lactulose solution contains deionised water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze.

6.5 Nature and contents of container

Polyethylene containers with polypropylene caps as closures.

Pack sizes: 50, 300, 500, 1000 and 2000ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Intrapharm Laboratories Ltd
60 Boughton Lane
Maidstone
Kent ME15 9QS
UK

8 MARKETING AUTHORISATION NUMBER

PA 997/8/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17 October 1995

Date of last renewal: 17 October 2005

10 DATE OF REVISION OF THE TEXT

November 2006