IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA0577/002/001
Case No: 2019767

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

McDermott Laboratories Ltd

35-36 Baldoyle Industrial Estate, **Grange Road**, **Dublin 13**, **Ireland**

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

GERELAX 3.35g/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 **09/03/2006** until **16/12/2006** .

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gerelax

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of the solution contains 3.30g Lactulose

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Oral solution

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For treatment of constipation and hepatic encephalopathy (hepatic coma).

4.2 Posology and method of adminstration

Route of administration: Oral
Gerelax may be taken with water or fruit juice

Initial dosage for constipation:

Adults:	*15ml (one sachet) twice daily*
Children 5 to 10 years:	10ml (two 5ml spoonful) twice daily
Children 2 to 5 years:	One 5ml spoonful twice daily

Initial dosage for hepatic encephalopathy:

Adults (including the elderly):	30 to 50ml three times daily
Children:	no dosage recommendations for this indication.

A doctor may wish to change these initial doses as ideally two or three soft stools should be produced daily and an acidic faecal pH.

4.3 Contraindications

Use in patients who require a galactose-free diet.

Use in patients with evidence of gastro-intestinal obstruction.

4.4 Special warnings and precautions for use

GERELAX should be used with caution in patients with lactose intolerance. Because of the physiological mode of action of GERELAX it may take up to 48 hours before effects are obtained. In addition there is a ‘carry-over’ effect

which may enable the patient to reduce the effective dose gradually over a period of time.

In the event of diarrhoea adequate fluid intake should be maintained during treatment, and the dosage reduced.

4.5 Interaction with other medicinal products and other forms of interaction

The product should not be taken with enteric coated mesalazine (5-ASA) as the lower stool pH may prevent the release of mesalazine.

The effect on 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 during pregnancy when considered necessary by the physician.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Side effects occur rarely. Cases of mild abdominal discomfort, cramps or flatulence have been reported following use of GERELAX, but these effects generally subside after the initial stage of treatment.

4.9 Overdose

No cases of intoxication due to deliberate or accidental overdose with GERELAX have been reported to the company.

No specific antidote. Symptomatic treatment should be given.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Lactulose is a semi synthetic disaccharide which is used in the treatment of constipation and in hepatic encephalopathy. Lactulose is broken down by colonic bacteria mainly into acetic and lactic acids which exert a local osmotic effect in the colon resulting in increased faecal bulk and stimulation of peristalsis. It may take up to 48 hours before an effect is obtained. When larger doses are given for hepatic encephalopathy the pH in the colon is reduced significantly by this acid production and the absorption of ammonium ions and other toxic nitrogenous compounds is decreased leading to a fall in blood-ammonia concentration.

5.2 Pharmacokinetic properties

Following oral administration, a negligible amount of lactulose is absorbed in the gastro-intestinal tract. It passes essentially unchanged into the large intestine where it is metabolised by saccharolytic bacteria, forming simple organic acids such as lactic and acetic acid. Urinary excretion has been reported to be 3% or less.

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water

6.2 Incompatibilities

None known

6.3 Shelf Life

1 year

6.4 Special precautions for storage

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

6.5 Nature and contents of container

HPDE bottle with white HDPE or polypropylene screw cap, containing 100, 150, 200, 300, 500, 1000 or 5000 ml of Lactulose Solution.
Amber glass bottle and white HDPE screw cap with polyethylene polycone liner, containing 100, 150, 200, 300, 500 or 1000ml of Lactulose Solution.
15 ml LDPE lined Aluminium foil sachets in packs of 14, 30, 50 or 100.

6.6 Instructions for use and handling

None

7 MARKETING AUTHORISATION HOLDER

McDermott Laboratories Limited trading as Gerard Laboratories,
35-36 Baldoyle Industrial Estate,
Grange Road,
Dublin 13
Ireland.

8 MARKETING AUTHORISATION NUMBER

PA 577/2/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisatioin: 16th December 1991
Date of last renewal: 16th December 2001

10 DATE OF REVISION OF THE TEXT

March 2005