IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0030/043/001
Case No: 2061350

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

Novartis Consumer Health UK Ltd

Wimblehurst Road, **Horsham**, **West Sussex RH12 5AB**, **England**

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

Lactulose Liquid Ph. Eur. 67% w/v 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 **12/06/2009**.

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

Lactulose Liquid Ph. Eur. 67% w/v Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of Lactulose Solution contains 3.35 g of Lactulose.

Excipients: also includes Lactose and Galactose <1.34g per 5ml

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Solution
Clear to almost colourless to pale yellow syrup.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Chronic constipation.

Chronic portal systemic encephalopathy.

4.2 Posology and method of administration

Chronic constipation
Because lactulose acts naturally to encourage the normal activity of the bowel, it may be two or three days before the full benefit of the treatment is obtained. It is important, therefore, to follow the dosage regime set out below.

Adults

Initially: 3-6 5ml spoonfuls for the first two to three days of treatment. (9 spoonfuls may be given in obstinate cases)

Maintenance: 2-3 5ml spoonfuls daily or according to the needs of the patient.

Children

Initially: 2-5 5ml spoonfuls for the first two to three days of treatment.

Maintenance: 1-3 5ml spoonfuls daily or according to the need of the patient.

Chronic portal systemic encephalopathy
6-10 5ml spoonfuls three times daily according to the requirements of the patient for adequate acidification of the colonic contents.

Use in the elderly
No evidence exists that elderly patients require different dosages or show different side-effects from younger patients.

4.3 Contraindications

In common with other preparations used for the treatment of constipation, lactulose solution should not be used in patients with gastrointestinal obstruction.
Lactulose solution should not be given to patients with galactosaemia or lactulose intolerance.

4.4 Special warnings and precautions for use

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

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

In the event of diarrhoea, dosage should be reduced to prevent loss of fluid and potassium and exacerbation of encephalopathy.

Long term use of this product is inadvisable except under medical supervision.

A dose of 5 ml contains approx. 19 cal, however since absorption from the gut is negligible, usual doses are unlikely to adversely affect diabetes.

Lactulose should be administered with care to patients who are intolerant to lactose.

Patients with rare hereditary problems of galactose intolerance e.g. galacotosaemia, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

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 lactose and prevent acidification of colonic content.

4.6 Pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Side-effects rarely occur after the administration of lactulose solution. Mild transient effects such as abdominal distension or cramps and flatulence, which subside after the initial stages of treatment, have occasionally been reported.

High doses may provoke nausea in some patients. This can be minimised by administration with water, fruit juice, or with meals.

4.9 Overdose

No cases of intoxication due to deliberate or accidental overdosage with lactulose solution have been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mode of action: Lactulose prevents the formation of hard stools and encourages normal bowel movement. Unlike traditional laxative preparations which act either on the innervation or musculature of the intestine or by bulk stimulus, lactulose provides a natural substrate for the saccharolytic bacterial flora in the colon.

5.2 Pharmacokinetic properties

Lactose is a disaccharide which is not hydrolysed in the small intestine. Therefore, it cannot be absorbed and is transported to the colon with water to retain the osmotic balance. In the colon, several species of bacteria can hydrolyse lactulose to the monosaccharides galactose and fructose.
By encouraging this normal metabolic activity of the bacteria, the osmotic pressure of the colon contents is doubled and more water is drawn into the bowel.

Further metabolism of the monosaccharides leads to this production of acetic and lactic 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.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to those already included in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sugars (lactose, galactose, tagatose and other ketonic sugars)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

HDPE plastic bottles, with polyethylene closure (polyethylene wad faced with PP. PVDC or PET lining).

Container sizes:
200 ml, 300 ml, 500 ml or 1 litre.

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

Dilution is not recommended.

7 MARKETING AUTHORISATION HOLDER

Novartis Consumer Health UK Limited
Trading as Novartis Consumer Health
Wimblehurst Road
Horsham
West Sussex
RH12 5AB
England

Trading as : Novartis Consumer Health

8 MARKETING AUTHORISATION NUMBER

PA 30/43/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of authorisation: 14 March 1988

Date of last renewal: 14 March 2008

10 DATE OF REVISION OF THE TEXT

November 2008