IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA0979/009/003
Case No: 2032524

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

Reckitt Benckiser Ireland Ltd

7 Riverwalk, **Citywest Business Campus**, **Dublin 24**, **Ireland**

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

FYBOGEL LEMON 3.5g Effervescent Granules

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 **06/02/2007**.

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

Fybogel Lemon 3.5g Effervescent Granules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains 3.5g ispaghula husk.
Also contains 16mg aspartame, per sachet.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Effervescent granules
Orange to buff-coloured granules with a lemon odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Clinical Indication: for the treatment of patients requiring a high fibre regimen.

4.2 Posology and method of administration

Fybogel Lemon is intended for oral administration in a suspension in a drink of water. The granules should be stirred into a glass of water and taken as soon as possible, preferably after meals.

Adults and children over 12 years:
One sachet or two 5 ml spoonfuls each morning and evening, preferably after meals.

Elderly:
There is no indication that dosage needs to be modified for the elderly.

Children 6 to 12 years:
Half to one level 5 ml spoonful, depending on age and size, morning and evening.

Children under 6 years:
To be taken only when prescribed by a doctor, half to one level 5 ml spoonful, depending on age and size, morning and evening.

4.3 Contraindications

Fybogel Lemon is contra-indicated in cases of intestinal obstruction, faecal impaction and colonic atony such as sanile mega-colon.

4.4 Special warnings and precautions for use

Due to its aspartame content Fybogel Lemon should not be given to patients with phenylketonuria.

If symptoms persist consult a doctor.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Fybogel Lemon may be used during pregnancy and lactation since the ispaghula husk is not absorbed from the gastrointestinal tract.

4.7 Effects on ability to drive and use machines

Not applicable in view of its physical mode of action.

4.8 Undesirable effects

Flatulence and bloating may be experienced during the first few days of treatment, but diminish during continued treatment.

4.9 Overdose

In the event of overdosage conservative measures should be taken. The patient may notice abdominal discomfort and flatulence, and attention should be paid to maintaining an adequate fluid intake, particularly if the granules have been taken without water contrary to administration instructions.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ispaghula husk is capable of absorbing up to 40 times its own weight in water *in vitro*, and part of its activity can be attributed to its action as a simple bulking agent. In addition, colonic bacteria are believed to use the hydrated material as a metabolic substrate. This results in an increase in the bacterial cell mass and consequent softening of the faeces.

5.2 Pharmacokinetic properties

The mode of action of Fybogel Lemon is physical and does not depend on absorption into the systemic circulation.

5.3 Preclinical safety data

No preclinical findings relevant to the prescriber have been reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid
Lemon flavour no. 1
Lemon flavour no. 4
Aspartame (E951)
Potassium Hydrogen Carbonate
Sodium Hydrogen Carbonate
Riboflavin Sodium Phosphate
Saccharin sodium
Polysorbate 80
Silica, colloidal anhydrous

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 30^{o}C. Store in the original package.

6.5 Nature and contents of container

Sachets of paper/aluminium foil/polythene/surlyn laminate enclosed in a cardboard outer carton.

Carton containing 10 and 30 sachets.

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

Reckitt Benckiser Ireland Limited
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 979/9/3

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 September 2001

Date of last renewal: 21 September 2006

10 DATE OF REVISION OF THE TEXT

February 2007