IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0100/047/003
Case No: 2071722

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

Forest Laboratories UK Ltd

Riverbridge House, **Crossways Business P**, **Kent, DA2 6SL**, **United Kingdom**

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

Bisodol Antacid Powder for Oral Suspension Magnesium carbonate, heavy 18 mg Magnesium carbonate, light 345mg Sodium hydrogen carbonate 532/5ml

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 **25/09/2009**.

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

Bisodol Antacid Powder for Oral Suspension
Magnesium carbonate, heavy 18 mg
Magnesium carbonate, light 345 mg
Sodium hydrogen carbonate 532 mg/5 ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml (0.9g) of powder contains:
18 mg Magnesium carbonate, heavy
345 mg Magnesium carbonate, light
532mg Sodium hydrogen carbonate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral suspension
A white powder with a slight odour and a taste of peppermint, for dispersion in water.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the relief of symptoms of indigestion, dyspepsia, heartburn, acidity and flatulence.

4.2 Posology and method of administration

Adults: One level teaspoon (5 ml) stirred into one third of a tumbler of water after meals or as required.

4.3 Contraindications

None stated.

4.4 Special warnings and precautions for use

- Persons with kidney disease or receiving medical treatment should consult their doctor before using.
- If symptoms persist, consult your doctor.
- Do not exceed the stated dose except on medical advice.

4.5 Interaction with other medicinal products and other forms of interaction

As with other antacids, Bisodol Antacid Powder may form complexes with certain drugs e.g. tetracyclines, digoxin and vitamins resulting in decreased absorption. Bisodol Antacid Powder should not be administered within two hours of taking such drugs.

4.6 Pregnancy and lactation

As with all medicines it is advisable to avoid Bisodol Antacid Powder in the first trimester of pregnancy.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Magnesium salts can have a laxative effect. The specific mixture of antacids is intended to avoid the lower gastro-intestinal effects seen with a single antacid preparation. No side effects are associated with sodium hydrogen carbonate except when taken in excess. Rebound hypersensitivity occurs with prolonged use.

4.9 Overdose

None stated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Sodium hydrogen carbonate and magnesium carbonate are antacids. They act by neutralising the hydrochloric acid produced by the stomach and thus reducing gastric and duodenal irritation.

5.2 Pharmacokinetic properties

Magnesium Carbonate

Magnesium carbonate reacts with gastric acid to form soluble magnesium chloride and carbon dioxide in the stomach. Some magnesium is absorbed but is usually excreted in the urine.

Sodium Hydrogen Carbonate

Administration of sodium hydrogen carbonate by mouth causes neutralisation of gastric acid with the production of carbon dioxide. Bicarbonate not involved in that reaction is absorbed and in the absence of a deficit of bicarbonate in the plasma, bicarbonate ions are excreted in the urine, which is rendered alkaline with an accompanying diuresis.

5.3 Preclinical safety data

None Stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Peppermint Essential Oil

6.2 Incompatibilities

As with other antacids, Bisodol Antacid Powder may form complexes with certain drugs e.g. tetracyclines, digoxin and vitamins resulting in decreased absorption. Bisodol Antacid Powder should not be administered within two hours of taking such drugs.

6.3 Shelf Life

5 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

White polypropylene securitainer (50g or 100g) with blue polyethylene caps with tamper evident tear off retaining strips.

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

Forest Laboratories UK Limited
Riverbridge House
Anchor Boulevard
Crossways Business Park
Dartford
Kent
DA2 6SL

8 MARKETING AUTHORISATION NUMBER

PA 100/47/3

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983

Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

September 2009