

**IRISH MEDICINES BOARD ACTS 1995 AND 2006**

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

**(S.I. No.540 of 2007)**

**PA0100/048/001**

Case No: 2072941

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, Anchor Boulevard, Crossways Business Park, Dartford, Kent DA2 6SL, United Kingdom**

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

**Bisodol Heartburn Chewable Tablets**

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 **19/01/2010**.

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

Bisodol Heartburn Chewable Tablets

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Magaldrate	400	mg per tablet
Alginic Acid	200	mg per tablet
Sodium Bicarbonate	100	mg per tablet

Excipients: Each tablet contains 0.8g sucrose and 27mg sodium.

For a full list of excipients, see section 6.1.

#### 3 PHARMACEUTICAL FORM

Chewable tablet

Round, white, smooth, bevel-edged edge tablet.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

For the relief of heartburn, including heartburn of pregnancy, reflux oesophagitis, hiatus hernia, regurgitation and all cases of epigastric distress associated with gastric reflux.

##### 4.2 Posology and method of administration

For oral administration.

Adults, the elderly and children over 12 years: suck or chew one or two tablets after meals and at bedtimes.

Children: 6 – 12 years: suck or chew one tablet after meals and at bedtime.

Children under 6 years: not recommended.

##### 4.3 Contraindications

None known.

##### 4.4 Special warnings and precautions for use

- Patients with renal impairment should not use this product except on the advice of a doctor.
- If symptoms persist, consult your doctor.
- Keep all medicines out of the reach of children.

## **4.5 Interaction with other medicinal products and other forms of interaction**

As with other antacids Bisodol Heartburn tablets may form complexes with certain drugs e.g. tetracyclines and iron tablets resulting in decreased absorption. Bisodol Heartburn tablets should not be administered within 2 hours of taking such drugs.

## **4.6 Pregnancy and lactation**

There are no contraindications to the use of Bisodol Heartburn Tablets in pregnancy or lactation; however, it is advisable to avoid the use of this preparation during the first trimester of pregnancy.

## **4.7 Effects on ability to drive and use machines**

No known effects.

## **4.8 Undesirable effects**

Abdominal distension and flatulence may occur.

## **4.9 Overdose**

Abdominal distension and diarrhoea may occur.

Hypermagnesaemia – intravenous administration of calcium salts.

# **5 PHARMACOLOGICAL PROPERTIES**

## **5.1 Pharmacodynamic properties**

Magaldrate acts locally in the gastrointestinal tract. It has no appreciable systemic activity.

Alginic Acid forms a highly viscous solution that floats on the surface of the gastric contents to act as a mechanical barrier to reflux, or to serve as the primary agent being refluxed.

Sodium bicarbonate is thought to react with alginic acid as the tablet is chewed, leading to the formulation of sodium alginate and carbon dioxide.

## **5.2 Pharmacokinetic properties**

Magaldrate reacts with acid in stages. The hydroxymagnesium is relatively rapidly converted to magnesium ion and the aluminate to hydrated aluminium hydroxide; the aluminium hydroxide then reacts more slowly to give a sustained antacid effect.

Anywhere from 15% to 30% of the magnesium ion is absorbed, however, in the normal person, magnesium ion is rapidly excreted by the kidney.

The reaction of magnesium hydroxide with hydrochloric acid produces magnesium chloride. Most of the magnesium chloride is converted to magnesium carbonate in the intestine and thus excreted.

In the stomach, aluminium hydroxide neutralises hydrochloric acid.

After the aluminium chloride enters the intestine some of the chloride is reabsorbed, and insoluble aluminium hydroxide and aluminium phosphate are formed.

When ingested, almost all of the alginic acid remains undigested and is excreted either unchanged or as an alginate.

Sodium Bicarbonate reacts with hydrochloric acid to form sodium chloride, and this together with any unreacted bicarbonate is absorbed and excreted in the urine.

### **5.3 Preclinical safety data**

Not applicable.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Compressible Sugar (Sucrose, maltodextrin)  
Microcrystalline Cellulose  
Maize Starch  
Magnesium Stearate  
Vanilla Flavour  
Cherry Flavour  
Cream Flavour

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf Life**

Three years.

### **6.4 Special precautions for storage**

Do not store above 25°C.

### **6.5 Nature and contents of container**

Blister packs of 250 micron uPVC\20 micron aluminium foil with 6 gsm heat seal coating. Packed in card cartons of 10 and 20 tablet packs.

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 100/48/1

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 23 April 1997

Date of last renewal: 23 April 2007

## **10 DATE OF REVISION OF THE TEXT**

January 2010.