

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Bisodol Indigestion Relief Tablets.

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

#### **Active Ingredients:**

Sodium Bicarbonate Ph.Eur	64mg/tablet
Calcium Carbonate Ph.Eur	522mg/tablet
Magnesium Carbonate Light Ph.Eur	68mg/tablet

### **3 PHARMACEUTICAL FORM**

Chewable tablet for oral administration.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

For relief of the symptoms of gastric hyperacidity, variously called indigestion, heartburn, dyspepsia and flatulence.

#### **4.2 Posology and method of administration**

Adults, the elderly and children over 12 years:  
Suck, slowly or chew one or two tablets as required.  
Children under 12 years: Not recommended.

#### **4.3 Contraindications**

Hypophosphataemia, and avoid in patients with heart failure or renal failure.

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

If symptoms persist, consult your doctor.

Keep all medicines out of the reach of children.

Not to be taken during the first three months of pregnancy.

#### Excipient(s)

#### Sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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

Antacids are known to reduce the absorption of certain medicines including tetracyclines and iron salts.

#### **4.6 Fertility, pregnancy and lactation**

Animal studies are insufficient with respect to effects on pregnancy/embryonal/foetal development/parturition and postnatal development.

Caution should be exercised when prescribing to pregnant women.

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

None Stated.

#### **4.8 Undesirable effects**

Calcium salts can have a constipating effect and magnesium salts can have a laxative effect. The specific mixture of antacids is intended to avoid the lower gastrointestinal effects seen with single antacid preparations. No side effects associated with sodium bicarbonate except when taken in excess.

Rebound hyperacidity may occur with prolonged dosage.

#### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme website at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

#### **4.9 Overdose**

Hypermagnesaemia - intravenous administration of calcium salts.

Hypernatraemia - give plenty of salt free fluids.

Hypercalcaemia - remove source of calcium.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

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

#### **5.2 Pharmacokinetic properties**

##### **Calcium Carbonate**

Calcium Carbonate is converted to calcium chloride by gastric acid. Some of the calcium is absorbed from the intestines but about 85% is reconverted to insoluble calcium salts, such as the carbonate, and is excreted in the faeces.

##### **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 rapidly in the urine.

##### **Sodium Bicarbonate**

Administration of sodium bicarbonate 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 that is rendered alkaline with an accompanying diuresis.

#### **5.3 Preclinical safety data**

The active ingredients in Bisodol Indigestion Relief Tablets have a well-documented safety record.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Saccharin Soluble BP  
Maize Starch Ph Eur  
Sugar Ph.Eur  
Calcium Stearate USNF  
Peppermint Essential Oil Hanningtons White Diamond (374611E)

### **6.2 Incompatibilities**

None Stated.

### **6.3 Shelf life**

Polypropylene packs: 36 months  
Other packs: 60 months.

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

Store at a temperature not exceeding 25°C.

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

Cellulose over wrapped shell and slide cardboard cartons.  
Pack sizes: 12, 30.

250 micron UPVC/20 micron coated aluminium blister packs in cardboard cartons.

Pack sizes: 24, 48.

Cellophane overwrapped carton of 5 rolls of 20 tablets in wax laminated foil with paper labels.

Pack size: 100.

Polypropylene roll holder with a polypropylene cap attached by a banding strip to the 100 tablet carton.

Amber glass bottle with black plastic cap.

Pack size: 250.

Rolls of 20 tablets in wax laminated foil with paper label.

Pack size: 20.

Polypropylene container and polypropylene lid.

Pack sizes: 30, 50.

Two rolls of 20 tablets in wax laminated foil packed together in a cardboard carton.

Pack size: 40.

Three rolls of 20 tablets in wax laminated foil packed together in a cardboard carton.

Pack size: 60

#### **6.6 Special precautions for disposal**

None.

### **7. MARKETING AUTHORISATION HOLDER**

Dexcel<sup>®</sup>-Pharma Ltd.,  
2nd Floor, Bourn, 1 Manor House Drive  
Coventry, CV1 2FX,  
UK

### **8 MARKETING AUTHORISATION NUMBER(S)**

PL 14017/0308

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

24/09/2004

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

24/12/2025