

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

JAWASIL ANTACID SUSPENSION ORANGE  
FLAVOUR

## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 10 ml contains:

Dried Aluminium Hydroxide gel BP ...600mg

Magnesium Trisilicate BP...300 mg Magnesium

Hydroxide BP...200mg

Dimethyl Polysiloxane USP...50 mg

## **3 PHARMACEUTICAL FORM**

Suspension

A rose-pink coloured suspension with An orange flavour.

## **4 CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

Jawasil Antacid suspension is indicated to treat the symptoms of too much stomach acid such as stomach upset, heartburn, and acid indigestion. It is also used to relieve symptoms of extra gas such as belching, bloating, and feelings of pressure/discomfort in the stomach/gut.

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

Adults: 1-2 table spoonful, 3 or 4 times daily

Children (6-12 years): 1-3 table spoonful, 3 or 4 times daily

### **4.3 Contraindications:**

It is not advisable for the patients suffering from gastrointestinal bleeding to consume Jawasil Antacid suspension. Jawasil Antacid suspension is also not used when patient consuming medication related to heart disorders. Should not be used in patients who are severely debilitated or suffering from kidney failure.

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

Pediatric population

In young children the use of magnesium hydroxide can produce a hypermagnesemia, especially if they present renal impairment or dehydration.

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

Antacids inhibit the absorption of tetracyclines and vitamins and should not be taken concomitantly.

Urine alkalinisation secondary to administration of magnesium hydroxide may modify excretion of some drugs; thus, increased excretion of salicylates has been seen.

#### **4.6 Pregnancy and lactation**

For Jawasil Antacid suspension no clinical data on exposed pregnancies are available.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.

Caution should be exercised when prescribing to pregnant women.

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

Not Stated

#### **4.8 Undesirable effects**

Gastrointestinal side-effects are uncommon. This formulation minimises the problems of diarrhoea and constipation.

Frequency not known:

Abdominal pain.

Frequency very rare:

Hypermagnesemia. Observed after prolonged administration of magnesium hydroxide to patients with renal impairment.

#### **4.9 Overdose**

Serious symptoms are unlikely to follow overdosage.

### **5 Pharmacological properties**

#### **5.1 Pharmacodynamic properties**

Aluminum Hydroxide: It is a non-systemic gastric antacid. It binds with phosphate in the gastrointestinal tract to inactivate pepsin and neutralize gastric acid. This action provides relief from symptoms associated with stomach ulcers and hyperacidity.

Magnesium Hydroxide: This compound has a laxative effect and is slightly alkaline in nature.

Simethicone: Simethicone acts by reducing the surface tension of gas bubbles thereby facilitating their expulsion. The Drug also prevents the accumulation of gas in the digestive tract.

Magnesium Trisilicate: Magnesium Trisilicate neutralizes excess acid present in the stomach to eliminate the symptoms such as acid indigestion, heartburn or sour stomach.

## **5.2 Pharmacokinetic properties**

Not applicable.

## **5.3 Preclinical safety data**

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

## **6 Pharmaceutical particulars**

### **6.1 List of excipients**

Erythrosine  
Aerosil-200  
Bromerol  
Citric acid  
Glycerine  
Gum guar  
Menthol  
Methyl Paraben  
Peppermint oil  
Propyl Paraben  
Propylene glycol  
Sodium CMC (DVP)  
Sorbitol 70% w/v  
Tween 80  
Orange Flavour

### **6.2 Incompatibilities**

None

### **6.3 Shelf life**

3 years

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

Store in cool & dry place, below 30°C.  
Protect from Light.

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

100ml and 200 ml Round White Opaque Bottles

## **7 MARKETING AUTHORISATION HOLDER**

### **JAWA INTERNATIONAL LIMITED**

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## **8 MANUFACTURED BY:**

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