

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

JAWASIL PLUS ANTACID SUSPENSION

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

Each 10 ml (Two Teaspoonful) contains:

Dried Aluminium Hydroxide gel BP ...600mg

Magnesium Trisilicate BP...300 mg

Magnesium Hydroxide BP...200mg

Dimethyl Polysiloxane USP...50 mg

Oxethazine BP... ..... 10 mg

## **3. PHARMACEUTICAL FORM**

Suspension

A White coloured and viscous suspension with a pleasant taste and menthol odour.

## **4. CLINICAL PARTICULARS**

### **Therapeutic indications**

Jawasil Plus 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.

### **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

**Contraindications:**

It is not advisable for the patients suffering from gastrointestinal bleeding to consume Jawasil Plus Antacid suspension. Jawasil Plus 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.

**Special warnings and precautions for use:**

Pediatric population

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

**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.

**Fertility, Pregnancy and lactation**

For Jawasil Plus 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.

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

Not Stated

**Undesirable effects**

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

Abdominal pain.

Frequency very rare:

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

### **Overdose**

Serious symptoms are unlikely to follow overdosage.

## **5. PHARMACOLOGICAL PROPERTIES**

### **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.

**Oxethazaine:** Oxethazaine is a topical anesthetic, which has been used clinically as an antacid.

### **Pharmacokinetic properties**

Not applicable.

### **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**

### **List of excipients**

Erythrosine

Aerosil-200

Bromerol

Citric acid

Glycerine

Gum guar

Menthol

Methyl Paraben

Oxethazine

Peppermint oil

Propyl Paraben

Propylene glycol

Sodium CMC (DVP)

Sorbitol 70% w/v

Tween 80

### **Incompatibilities**

None

### **Shelf life**

3 years

### **Special precautions for storage** Store

in cool & dry place, below 30°C.

Protect from Light.

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

100 ml Amber Bottles

## **7. MARKETING AUTHORISATION HOLDER**

### **JAWA INTERNATIONAL LIMITED**

Jawa House Compound, Plot 6 Abimbola Way,

Isolo Industrial Estate, Isolo,

Lagos, Nigeria

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## **8. MANUFACTURED BY:**

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