

1 NAME OF THE MEDICINAL PRODUCT

JAWASIL ANTACID SUSPENSION

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 PolysiloxaneUSP...50 mg

3 PHARMACEUTICAL FORM

Suspension

A rose-pink coloured suspension with a pleasant taste and menthol smell.

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

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

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