

SMPC FOR EB EVACID SUSPENSION

1. Name of the medicinal product

EB EVACID SUSPENSION

1. Qualitative and quantitative composition

Dried Aluminum Hydroxide Gel USP	250mg
Eq to Aluminum Hydroxide	191.25mg
Magnesium Hydroxide USP	250mg
Simethicone Emulsion USP	50mg
Flavoured Syrupy Base	q.s.
Colour : Erythrosine	

Pharmaceutical form Mixture

2. Clinical particulars

2.1 Therapeutic indications

For the rapid relief from heartburn, dyspepsia and flatulence associated with indigestion.

2.2 Posology and method of administration Oral.

RECOMMENDED DOSE

Children: 1-6 years – 5ml three times daily

6-12years - 10ml three times daily

Adults : 12 years and over – 15ml three times daily or as directed by the physician.

Directions for use: shake the bottle.

DOSAGE SCHEDULE

To be taken three times a day or as directed by the physician.

Use the measuring cup provided.

2.3 Contraindications

Evacid Suspension should not be administered in patients with renal aution in patients failure *or* hypophosphataemia or in those who are severely debilitated. It is also contraindicated in alkalosis and hypermagnesaemia, where abdominal distention may be due to partial or complete intestinal obstruction.

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2.4 Warnings and precautions for use

Aluminium hydroxide may cause constipation due to its astringent action; this effect may be balanced by the cathartic effect of the magnesium salts. Aluminum hydroxide may lead to a phosphate depletion syndrome, particularly in patients on a low phosphate diet e.g. malnutrition.

Magnesium salts may cause central nervous depression in the presence renal insufficiency and should be used with extreme caution in patient with kidney disease.

Patients with rare hereditary problems of fructose intolerance should not take this medicine. In patients with renal impairment, plasma levels of both aluminum and magnesium increase. In these patients, a long-term exposure to high doses of aluminum and magnesium salts may lead to encephalopathy, dementia, microcytes anemia or worsen dialysis-induced osteomalacia.

The prolonged use of antacids in patients with renal failure should be avoided. Aluminum hydroxide may be unsafe in patients with porphyria undergoing hemodialysis because it has been shown that aluminum may be involved in porphyrin metabolism abnormalities.

Evacid Suspension should be used with caution in patients with kidney disease.

The following warnings and precautions appear on the labels:

Keep out of the reach and sight of children.

If symptoms persist consult your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

Aluminum hydroxide may form complexes with certain drugs, eg tetracyclines, digoxin and vitamins, resulting in decreased absorption. This should be borne in mind when concomitant administration is considered. Concomitant use with quinidines may increase the serum levels of quinidine and lead to quinidine overdose. Aluminium- containing antacids may prevent the proper absorption of H₂ antagonists, atenolol, chloroquine, cyclines, diflunisal, digoxin, diphosphonates, ethambutol, fluoroquinolones, sodium fluoride, glucocorticoids, indometacin, isoniazide, kayexalate, ketoconazole, lincosamides, metoprolol, neuroleptics phenothiazines, penicillamine, propranolol, iron salts.

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4.6 Pregnancy and lactation

It is advised to avoid antacid preparation in the first trimester of pregnancy.

4.7 Effects on ability to drive and use machines

None.

4.8 Side effects and Special Precautions

Gastrointestinal side effects are uncommon. Occasionally, if excessive amount is consumed, diarrhea, constipation or regurgitation may occur.

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.

4.9 Overdose

Overdose, or excessive or prolonged intake of magnesium containing antacids may give rise to hypermagnesaemia, and excessive administration of sodium hydrogen carbonate may lead to hypokalaemia and metabolic alkalosis, especially in patients with renal insufficiency.

Symptoms of hypermagnesaemia include nausea, vomiting, flushing of the skin, thirst, drowsiness, hypotension, confusion, muscle weakness, CNS and respiratory depression, hyporeflexia, peripheral vasodilatation, bradycardia, cardiac arrhythmias, coma and cardiac arrest.

Symptoms of hypokalaemia and metabolic alkalosis include mood changes, tiredness, shortness of breath, muscle weakness and irregular heart beat. Muscle hypertonicity, twitching and tetany may develop, especially in hypocalcaemic patients. Excessive doses of sodium salts may lead to sodium overloading and hyperosmolality.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Evacid Suspension is the mixture of non-systemic acid neutralizing substances and anti-flatulent.

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5.2 Pharmacokinetic properties

The absorption of aluminium and magnesium from antacids is small. Aluminium hydroxide is slowly converted to aluminium chloride in the stomach. Some absorption of soluble aluminium salts occurs in the gastro-intestinal tract with urinary excretion. Any absorbed magnesium is likewise excreted in the urine.

5.3 Preclinical safety data None Known.

6. Pharmaceutical particulars 6.1 List of excipients Dried Aluminium Hydroxide Gel USP, Magnesium Hydroxide USP, Simethicone Emulsion USP.

Flavoured Syrupy Base

Colour : Erythrosine.

6.2 Incompatibilities: None.

6.3 Shelf life: 36months.

6.4 Special precautions for storage:

Store below 30°C, away from light

6.5 Nature and contents container

200ml: Flint pet bottle with white 28mm ROPP cap with EB logo.

6.6 Special precautions for disposal and other handling :

None.

7. Marketing authorisation holder Evans Baroque Ltd

8. Marketing authorisation number(s)

NA

9. Date of first authorisation/renewal of the authorisation

NA

10. Date of revision of the text

NA