

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

**EBECID SUSPENSION**

## **2. QUALITATIVE & QUANTITATIVE COMPOSITION**

### **COMPOSITION:**

Each 5 ml of suspension contains:

Magnesium Hydroxide BP .... 250 mg

Dried Aluminium Hydroxide Gel BP .... 250 mg

Simethicone USP .... 50 mg

Syrup Base .... Q. S.

Colour: Erythrosine (IHS)

### **Excipients:**

1. Dried aluminum hydroxide gel
2. Magnesium hydroxide
3. Simethicone 30%
4. Sorbitol 70% solution
5. Glycerin
6. Sodium methyl paraben
7. Sodium propyl paraben
8. Sodium carboxy methyl cellulose
9. Bronopol
10. Sodium saccharin
11. Menthol
12. Colour erythrosine supra
13. Peppermint oil
14. Spearmint oil
15. Purified Water

### **3. PHARMACEUTICAL FORM**

Oral Liquid Suspension

### **4. CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

EBECID SUSPENSION acts as an antacid in dyspepsia and is used for the symptomatic relief of hyperacidity associated with peptic ulceration, gastritis, oesophageal reflux with heartburn and gastric hyperacidity and as Antiflatulent to alleviate the symptoms of gas including postoperative gas pain.

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

Adults: 10 ml- 15 ml (2-3 Teaspoonful) twice a day after each meal or when required.

Children (Above 5 years of age): 5 ml-10 ml (1-2 Teaspoonful) twice a day after meals or as directed by the Physician.

#### **4.3 Contraindications**

The use of Aluminium or magnesium-containing antacids is contra-indicated in patients with symptoms of appendicitis since these medicines may increase the danger of perforation or rupture due to their constipating or laxative effects. The use of magnesium-containing antacids is contra-indicated in patients with severe renal function impairment due to increased danger of occurrence of hypermagnesaemia.

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

The use of magnesium-containing antacids in patients with mild to moderate renal impairment should be carefully monitored due to a possible increased danger of hypermagnesaemia.

In patients with chronic renal failure, hyparaluminaemia may occur.

Encephalopathy and dementia may occur in patients with poor renal function or patients on dialysis, due to an increase in plasma concentration of Aluminium.

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

EBECID SUSPENSION may interact with the following drugs:

Anticoagulants (e.g. warfarin), citrate salts (found in soma calcium supplements, antacids, and laxatives), or quinidine because their actions and side effects may be increased by EBECID SUSPENSION.

Tetracycline, iron salts, isoniazid, ethambutol, some anti-muscarinic drugs, benzodiazepines, phenothiazines, ranitidine, indomethacin, phenytoin, nitrofurantoin, Vitamin A. fluoride and phosphate because their effectiveness may be decreased by EBECID SUSPENSION.

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

Safety in pregnancy and lactation has not been established. Use of antacids should be avoided in the first trimester of pregnancy. Caution should be exercised when prescribing to pregnant and lactating women.

Because of the limited maternal absorption, when used as recommended, minimal amounts, if any, of Aluminium hydroxide and magnesium salt combinations are expected to be excreted into breast milk.

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

There are no effects on ability to drive or use machines.

#### **4.8 Undesirable effects**

Sensitivity reactions including skin eruptions (dermatitis, urticaria), pruritus, glossitis, angioedema and collapse have been reported. Magnesium-containing antacids may cause diarrhoea. Aluminium-containing antacids may cause constipation.

#### **4.9 Overdose**

Overdose may cause dizziness, faintness or drowsiness. Treatment is symptomatic and supportive.

### **5. Pharmacological properties**

#### **5.1 Pharmacodynamic properties**

EBECID SUSPENSION is an antacid suspension which neutralizes gastric acid and raise pH of gastric contents.

Alginic acid is a foaming agent that floats on top of the stomach contents. This may help keep stomach juices from coming in contact with the esophagus. Dried Aluminium Hydroxide Gel and Magnesium hydroxide react chemically to neutralize or buffer existing quantities of acid, but have no direct effect on its production. This action increases gastric pH.

Simethicone works by breaking up gas bubbles, which makes gas easier to eliminate. Either alone or with antacid mixture it acts as antifoaming agent to reduce flatulence. It is a silicon polymer that lowers surface tension and allows the small bubbles of froth to coalesce into large bubbles that can be more easily passed up from the stomach or down from the colon.

#### **5.2 Pharmacokinetic properties**

Aluminum Hydroxide Gel: Small amounts of the aluminum in aluminum hydroxide gel are absorbed from the intestine.

Magnesium Hydroxide: Approximately 10% of the magnesium in magnesium hydroxide (magnesia) is absorbed from the intestine.

Simethicone: Simethicone is not absorbed following oral administration. It does not interfere with the absorption of nutrients or with gastric secretion. Simethicone is excreted unchanged in feces.

### **5.3 Preclinical safety data**

Not known.

## **6. Pharmaceutical particulars**

### **6.1 List of excipients**

Sorbitol 70% solution

Glycerin

Sodium Methyl Paraben

Sodium Propyl Paraben

Sodium Carboxymethyl Cellulose

Bronopol

Sodium Saccharin

Menthol

Colour Erythrosine Supra

Peppermint Oil

Spearmint Oil

Purified water

**6.2 Incompatibilities:** Not Applicable.

**6.3 Shelf life:** 36 months.

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

Store below 30°C in a cool, dry and dark place.

Keep all medicines out of reach of children.

Keep bottle tightly closed.

SHAKE WELL BEFORE USE.

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

200 ml amber coloured PET bottle in a carton along with pack insert.

### **6.6 Special precautions for disposal and other handling**

No special requirements for disposal. Any unused medicinal product or waste material should be

disposed of in accordance with local requirements.

**7. Manufacturer:**

**Name & address:**

**Lesanto Laboratories.**

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Survey No. 53, Palghar (E),

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**8. Marketing Authorisation Holder:**

**Mercury Healthcare Pvt. Ltd.**

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