AZMUCAINE SUSPENSION

Aluminium Hydroxide, Magnesium Hydroxide, Sodium Alginate, Oxetacaine & Dimethicone Suspension

Summary of Product Characteristics

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1 NAME OF THE MEDICINAL PRODUCT

AZMUCAINE SUSPENSION

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:
Aluminium Hydroxide BP……..……300 mg
Magnesium Hydroxide BP……...…….150 mg
Sodium Alginate BP…… 100 mg
Oxetacaine BP…….……. 10 mg
Dimethicone BP…… 125 mg
Excipients…...……...……... q.s.
Approved colour and Flavours added.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Antacid suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indication.

Antacid therapy in gastric and duodenal ulcer, gastritis, heartburn and gastric hyperacidity.

4.2 Posology and method of administration.

Adults (including the elderly):
10 – 20 ml taken 20 minutes to one hour after meals and at bedtime or as required. AZMUCAINE can be taken with water or milk if required.
Children:
Not recommended for children under 14 years.
Oral administration.

4.3 Contraindications

AZMUCAINE should not be used in patients who are severely debilitated or suffering from renal insufficiency, or if there is severe abdominal pain and/or the possibility of bowel obstruction.

4.4 Special warnings and precaution for use.

In patients with renal impairment, plasma levels of both aluminium and magnesium increase. In these patients, a long-term exposure to high doses of aluminium and magnesium salts may lead to dementia, microcytic anemia.

Aluminum hydroxide may be unsafe in patients with porphyria undergoing hemodialysis.

4.5 Interaction with other medicinal product and other forms of interaction.

Antacids are known to interfere with the absorption of certain drugs including tetracyclines, vitamins, ciprofloxacin, ketoconazole, hydroxychloroquine, chloroquine, chlorpromazine and rifampicin.

Aluminum hydroxide and citrates may result in increased aluminum levels, especially in patients with renal impairment.

4.6 Pregnancy and Lactation.

No clinical data on exposed pregnancies are available. Use of antacids should be avoided in the first trimester of pregnancy. Caution should be exercised when prescribing to pregnant and lactating women.

Magnesium is considered as compatible with lactation

4.7 Effect on the ability to drive and use machine.

None stated.

4.8 Undesirable effect.

Gastrointestinal side effects are uncommon. However, occasional diarrhoea or constipation may occur if use is excessive.

4.9 Overdose.

Serious symptoms are unlikely following overdose. Discontinue medication and correct fluid deficiency if necessary.
Treatment of magnesium overdose: consider administration of IV Calcium Gluconate, rehydration and forced diuresis. In case of renal deficiency, haemodialysis or peritoneal dialysis is necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties.

AZMUCAINE is a balanced mixture of two antacids; aluminium hydroxide is a slow-acting antacid and magnesium hydroxide is a quick-acting one. The two are frequently combined in antacid mixtures. Aluminium hydroxide on its own is an astringent and may cause constipation. This effect is balanced by the effect of magnesium hydroxide, which, in common with other magnesium salts, may cause diarrhoea. Gastro-intestinal side effects are thus rare with AZMUCAINE and this makes it especially suitable when long term therapy is necessary.

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. Aluminium containing antacids should not be administered to patients with renal impairment where increased plasma concentration may occur.

5.3 Preclinical safety data.

No relevant data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Methyl Paraben BP
Sodium Propyl Paraben BP
Sucrose BP
Polysorbate 80 (Tween 80) BP
Colour Erythromycin supra
Sorbitol solution 70% (Non- crystallizing) BP
Propylene Glycol BP
Xanthan Gum BP
Colloidal silicon Dioxide BP
Bronopol BP
Sodium Citrate BP
Citric acid Monohydrate BP
Flavoured Mixed Fruit
Purified water BP

6.2 Incompatibilities

unknown

6.3 Shelf-life

36 months

6.4 Special precautions for storage

Do not store above 30°C. Store in a dry place.

6.5 Nature and composition of immediate packaging

Pink colour viscous liquid with a characteristic flavor packing in 100 ml labeled PET bottle with screw caping, which is further packed in a carton with a leaflet.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

7 MARKETING AUTHORISATION HOLDER

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