SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product

ACIGUARD ANTACID SUSPENSION

2. Qualitative and Quantitative Composition

Each 5ml contains:
Dried Aluminium Hydroxide BP……...300mg
Magnesium Hydroxide BP ……100mg
Magnesium Trisilicate BP…….150mg
Simeticone for oral use BP……25mg

For full the list of excipients, see section 6.1.

3. Pharmaceutical form

Suspension

4. Clinical particulars

4.1 Therapeutic indications

Aciguard Antacid Suspension is indicated for:

(a) Symptomatic management and relief of pain in hyperacidity conditions such as heart burn, indigestion, peptic ulcer, reflux oesophagitis, flatulent dyspepsia.

(b) Treatment of peptic ulcer alone or with Cimetidine.

(c) Maintenance therapy in peptic ulcer after healing of peptic ulcer with Cimetidine treatment course.

4.2 Posology and method of administration

Posology

Children: 6 –1 2years – 5ml to 10ml of three to four time daily after meals.

Adult: 10ml to 20ml of suspension three to four times daily after meals

Shake well before use.

4.3 Contraindications

Aciguard Suspension is contraindicated in patients with hypophosphataemia, intestinal obstruction and hypersensitivity to any of the ingredients. It should be used with caution in patients with renal impairment.

4.4 Special warnings and precautions for use

Aluminium hydroxide may cause constipation and magnesium salts overdose may cause hypermotility of the bowel; large doses of this product may trigger or aggravate intestinal obstruction and ileus in patients at higher risk such as those with renal impairment, or the elderly. Aluminium hydroxide is not well absorbed from the gastrointestinal tract systemic effects are therefore rare in patients with normal renal function. However, excessive doses or long- term use, or even normal doses in patients with low-phosphorus diets may lead to phosphate depletion (due to aluminium-phosphate binding) accompanied by increased bone resorption and hypercalciuria with the risk of osteomalacia. Medical advice is recommended in case of long-term use or patients with risk of phosphate depletion.

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

4.5 Drugs interactions

Antacids commonly interfere with the absorption of wide range of orally taken drugs such as phenytoin, iron supplements, tetracycline penicillamine, digoxin, I.N.H, phenothiazine, and fat soluble vitamin.

Caution is advised when used concomitantly with polystyrene sulphonate due to the potential risk of reduced effectiveness of the resin in binding potassium, of metabolic alkalosis in patients with renal failure (reported with aluminium hydroxide and magnesium hydroxide), and of intestinal obstruction (reported with aluminium hydroxide).

Aluminium hydroxide and citrates may result in increased aluminium level, especially in patients with renal impairment.

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

Pregnancy

There are no or limited amount of data from the use of aluminium hydroxide and magnesium hydroxide in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.30). Aciguard is not recommended during the first trimester of pregnancy and in women of childbearing potential not using contraception. Caution should be exercised when prescribing to pregnant and lactating women.

Lactation

Because of the limited maternal absorption, when used as recommended, aluminium hydroxide and magnesium salt combination are considered compatible with lactation.

No effects on the breastfed newborn/ infant are anticipated since the systemic exposure of the breast-feeding woman to aluminium hydroxide and magnesium hydroxide is negligible.

4.7 Effects on ability to drive and use machines

Aciguard Suspension has no influence on the ability to drive and use machine.

4.8 Undesirable effects

No significant side effects but there is slight possibility of diarrhea and belching. In patients with impaired renal function and gastrojejunal stoma, rapid absorption of magnesium may result in hypermagnesaemia, producing symptoms of muscular weakness, hypotension, ECG changes, sedation, confusion and severe cases, respiratory paralysis and adrenergic cardiac presystole. Lon-term, excessive use has been associated with the development of silica based renal calculi.

4.9 Overdose

Serious symptoms are unlikely following overdose. Discontinue medication and correct fluid deficiency if necessary.
Reported symptoms of acute overdose with aluminum hydroxides and magnesium salts combination include diarrhea, abdominal pain, vomiting.
Large doses of this product may trigger or aggravate intestinal obstruction and ileus in patients at risk (see section 4.4).

Aluminium and magnesium are eliminated through urinary route; treatment of acute overdose consists of administration of IV Calcium Gluconate, rehydration and forced diuresis. In case of renal function deficiency, haemodialysis or peritoneal dialysis is necessary.

5 Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antacid; aluminium compound combinations

Aciguard is balanced mixture of two antacids; aluminium hydroxide is 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 astringent and may cause constipation. This effect is balance by the effect of magnesium hydroxide, which, in common with other magnesium salts, may cause diarrhea. Gastro-intestinal side effect are thus rare with Aciguard Suspension when long term therapy is necessary.

5.2 Pharmacokinetic properties

Absorption of aluminium and magnesium from antacid is small. Aluminium hydroxide is slowly converted to aluminium chloride in the stomach. Some absorption of soluble aluminium salts occurs in the gastrointestinal tract with urinary excretion. Any absorbed magnesium is likewise excreted in urine. Aluminium containing antacids should not be administered to patients with renal impairment where increased plasma concentration may occur.

5.3 Preclinical safety data

Non-clinical data are limited and are considered insufficient with respect to repeated dose toxicity, genotoxicity and toxicity to reproduction and development.

6 Pharmaceutical particulars

6.1 list of excipients:

S. No	Composition	Reference
1.	Methyl Paraben	**BP**
2.	Propyl Paraben	**BP**
3.	Xanthan gum	**BP**
4.	Menthol Crystals	**BP**
5.	Colloidal Silicon dioxide (Aerosil 200)	**BP**
6.	Glycerin	**BP**
7.	Liquid sorbitol (non-crystallizing)	**BP**
8.	Citric acid Monohydrate	**BP**
9.	Peppermint oil	**BP**
10.	Propylene glycol	**BP**
11.	Allura Red	**IHS**
12.	Purified water	**BP**

6.2 incompatibility

Antacids commonly interfere with the absorption of a wide range of orally taken drugs such as phenytoin, iron supplements, tetracycline, penicillamine, digoxin, I.N.H, phenothiazine, and fat soluble vitamins. In view of the potential of antacids to affect the absorption of many other drugs, it is advisable that any other drugs to be taken orally concurrently with Aciguard Suspension should be administered at least half to one before the antacid is taken.

6.3 Shelf life

3 years

6.4 Special precaution for storage

Store below 30°C

Keep all the medicines away from the reach of children

6.5 Nature and contents of container

200ml and 100ml bottle

6.6 Special precautions for disposal and other handling

No special requirement**.**

7. Marketing authorisation holder

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