## **Ariscon**

Sodium Alginate BP Sodium Bicarbonate BP Calcium Carbonate USP

Composition: Each 10 ml suspension contains Sodium Alginate BP 500 mg, Sodium Bicarbonate BP 267 mg & Calcium Carbonate USP 160 mg.

Pharmacology: The mode of action of the product is physical and does not depend on absorption into the systemic circulation. On ingestion, the product reacts rapidly with gastric acid to form a raft of Alginic acid gel having a near neutral pH and which floats on the stomach contents quickly and effectively impeding gastro-esophageal reflux, for up to 4 hours. In severe cases, the raft itself may be refluxed into the esophagus in preference to the stomach contents and exerts a demulcent effect.

**Indications:** Gastric reflux, heartburn, indigestion, flatulence associated with gastric reflux, heartburn of pregnancy, all cases of epigastric and retrosternal distress where the underlying cause is gastric reflux.

## Dosage & Administration:

Adult and children over 12 years: 10-20 ml after meals and at bedtime, up to 4 times a day.

Children 6 to 12 years: 5-10 ml after meals and at bedtime, up to 4 times a day.

Children under 6 years: Not recommended.

Elderly: No dosage modification is required for this age group.

**Contraindications:** This product is contraindicated in patients with known or suspected hypersensitivity to the active ingredients or to any of the excipients.

**Precautions:** If symptoms do not improve after 7 days, the clinical situation should be reviewed. Each 10 ml dose has a sodium content of 142.6 mg (6.2 mmol). This should be taken into account when a highly restricted salt diet is recommended. e.g. in some cases of congestive cardiac failure and renal impairment. Each 10 ml dose contains 160 mg (1.6 mmol) of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

Side Effects: In addition to the desired effect of the drug, some side effects may appear such as: constipation, flatulence, stomach cramp or belching. In these cases, consult a physician. If too big dose has been taken, there might appear a sensation of swelling. In this case, it is advisable to consult a physician.

## Use in Pregnancy, Lactation & Fertility:

Pregnancy: Clinical studies in more than 500 pregnant women as well as a large amount of data from post-marketing experience indicate no malformative nor feto/neonatal toxicity of the active ingredients. This drug can be used during pregnancy, if clinically needed.

Breast feeding: No effects of the active substances have been shown in breastfed newborns/infants of treated mothers. This drug can be used during breast-feeding.

Fertility: Pre-clinical investigations have revealed alginate has no negative effect on parental or offspring fertility or reproduction. Clinical data do not suggest that this drug has an effect on human fertility.

**Drug Interactions:** A time-interval of 2 hours should be considered between this drug intake and the administration of other medicinal products, especially tetracyclines, digoxine, fluoroquinolone, iron salt, ketoconazole, neuroleptics, thyroid hormones, penicillamine, beta-blockers (atenolol, metoprolol, propranolol), glucocorticoid, chloroquine and biphosphonates (diphosphonates) and estramustine.

**Overdosage:** In the event of overdose, symptomatic treatment should be given. The patient may notice abdominal distension.

**Storage:** Store below 30°C, Keep in dry place & protect from light. Keep out of the reach of children. Do not refrigerate or freeze.

Packing: Each commercial box contains a bottle containing 200 ml suspension with a measuring cup.

