Gastrum™

Sodium Alginate BP, Sodium Bicarbonate BP and Calcium Carbonate USP Oral Suspension

DESCRIPTION:
The product is a combination of two antacids (Calcium Carbonate and Sodium Bicarbonate) and an Alginate. The mode of action of the product is physical and does not depend on absorption into the systemic circulation. On ingestion, the medicinal product reacts rapidly with gastric acid to form a raft of Alginic Acid gel having a near neutral pH and studies have shown that the raft interacts with and caps the "acid pocket in the stomach, reducing esophageal acid exposure. The raft floats on the stomach contents effectively impeding gastro-esophageal reflux, for up to 4 hours, and protecting the esophagus from Acid, Pepsin and Bile. In severe cases the raft itself may be refluxed into the esophagus, in preference to the stomach contents, and exert a demulcent effect. In addition in vitro evidence has shown that the raft has a secondary action and is able to entrap bile and pepsin within it structure, further protecting the esophagus from these gastric components. Calcium Carbonate neutralizes gastric acid to provide fast relief from indigestion and heartburn. This effect is increased by the addition of Sodium Bicarbonate which also has a neutralizing action.

INDICATION
Acid regurgitation, heartburn, indigestion and hyperacidity. It can also be used to treat the symptoms of Gastro-esophageal reflux during concomitant treatment with or following withdrawal of acid suppressing therapy.

DOSAGE AND ADMINISTRATION
Adults and children 12 years and over: 10-20 mL (2-4 spoonfuls) after meals and at bedtime, up to four times per day. **Children under 12 years:** Should be given only on medical advice.

USE IN SPECIAL POPULATION
Pregnancy: Clinical studies in 281 pregnant women did not demonstrate any significant adverse effects on the course of pregnancy or on the health of the foetus/new-born child. This product may be used during pregnancy, if clinically needed.
Breastfeeding: No effects of the active substances have been shown in breastfed newborns/infants of treated mothers. This product can be used during breast feeding if clinically needed.
Elderly: No dose modifications necessary.
Hepatic Impairment: No dose modification necessary.
Renal Insufficiency: Caution if highly restricted salt diet is necessary.

SIDE EFFECTS
Very rare (frequency: <1/10,000): Anaphylactic reaction, anaphylactoid reaction, urticaria, bronchospasm.

CONTRAINDICATION
This product is contraindicated in patients with known or suspected hypersensitivity to the active substances or to any of the excipients

DRUG INTERACTION
A time-interval of 2 hours should be considered between intake of this product and the administration of other medicinal products, especially Anti-histamines, Tetracyclines, Digoxine, Fluoroquinolones, Iron salts, Thyroid hormones Ketoconazole, Neuroleptics, Thyroxine, Penicillamine Beta-blockers, Glucocorticoid, Chloroquine, Diphosphonates, Estramustine etc.

PRECAUTION AND WARNING
This product contains 127.88 mg Sodium per 10 mL dose, equivalent to 6.4% of the WHO recommended maximum daily intake for Sodium. The maximum daily dose of this product is equivalent to 51.15% of the WHO recommended maximum daily intake for Sodium. This product is considered high in Sodium. This should be particularly taken into account for those on a low salt diet (e.g. in some cases of congestive heart failure and renal impairment). Each 20 mL contains 260 mg (6.5 mmol) of Calcium. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent Calcium containing renal calculi.

STORAGE
Keep away from light and wet place, do not store above 30 °C temperature. Keep out of the reach of children.

PACKAGING
Gastrum™ Oral Suspension: Box containing one bottle of 200 mL suspension. Each 10 mL suspension contains Sodium Alginate BP 500 mg, Sodium Bicarbonate BP 213 mg and Calcium Carbonate USP 325 mg.

SK+F

Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
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TM. TRADEMARK
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