Gaviplus®

Sodium Alginate, Sodium Bicarbonate, Calcium Carbonate

COMPOSITION:

Gaviplus: Each 10 ml suspension contains Sodium Alginate USP 500 mg and also contains Sodium Bicarbonate USP 267 mg & Calcium Carbonate BP 160 mg.

Gaviplus DX: Each 10 ml suspension contains Sodium Alginate USP 500 mg and also contains Sodium Bicarbonate USP 213 mg & Calcium Carbonate BP 325 mg.

PHARMACOLOGY:

The mode of action of the Gaviplus ® 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 exert a demulcent effect.

INDICATION:

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

DOSE & ADMINISTRATION:

For oral administration.

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

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

Children under 6 years: Not recommended.

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

CONTRAINDICATION:

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

WARNING & PRECAUTION:

If symptoms do not improve after 7 days, the clinical situation should be reviewed. Each 10 ml dose has a Sodium content of 141 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 hypercalcemia, 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:

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.

USE IN CHILDREN AND ADOLESCENTS:

Alginate is not recommended to use for children under 6 years old.

DRUG INTERACTION:

A time-interval of 2 hours should be considered between this drug intake & the administration of other medicinal products, especially Tetracyclines, Digoxin, Fluoroquinolone, Iron salt, Ketoconazole, Neuroleptics, Thyroid Hormones, Penicillamine, beta-blockers (Atenolol, Metoprolol, Propranolol), Glucocorticoid, Chloroquine and Biphosphonates (diphosphonates) and Estramustine.

OVERDOSE:

In the event of over dosage symptomatic treatment should be given. The patient may notice abdominal distension.

STORAGE:

Store in a dry and cool place below 30^0 C temperature and keep away from light and moisture. Keep out of reach of children. Do not refrigerate.

PACKING:

Each commercial box contains a PET bottle contains 200 ml suspension with a 20 ml measuring cup.

Manufactured by

Team Pharmaceuticals Ltd.

B 75-79, BSCIC, Rajshahi, Bangladesh

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