Gavipex

Sodium Alginate+Sodium Bicarbonate
Calcium Carbonate

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

Pharmacology
The mode of action of **Gavipex** 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, 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, Regurgitation, Indigestion, Belching, Bloating, Heartburn of Pregnancy, all cases of Epigastric and Retrosternal Distress where the underlying cause is Gastric Reflux.

Dosage & 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:* Adult dosage is recommendation for elderly patient.

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

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 considered 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 Effect
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 with a physician. If too large dose has been taken, there might appear a sensation of swelling. In this case, it is advisable to consult with a physician.

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

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

Storage
Keep away from light & moisture and store below 30° C. Keep out of the reach of children. Do not refrigerate or freeze.

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

Apex™
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