

Onvicon Plus/DX

Sodium Alginate USP, Sodium Bicarbonate BP &
Calcium Carbonate BP

Composition

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

Onvicon DX Suspension: Each 10 ml suspension contains Sodium Alginate USP 500 mg, Sodium Bicarbonate BP 213 mg & Calcium Carbonate BP 325 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 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

a) *Route of administration:* Oral

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.

Contra-indication

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

Warning and precaution

If symptoms do not improve after 7 days, the clinical situation should be reviewed.

Onvicon plus contains (6.2 mmol/10 ml) of sodium & Onvicon DX contains (5.56 mmol/10 ml) of sodium. 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.

Onvicon plus contains (1.6 mmol/10 ml) of Calcium Carbonate & Onvicon DX contains (3.25 mmol/10 ml) of Calcium Carbonate. Care needs to be taken in treating patients with hypercalcemia, nephrocalcinosis and recurrent calcium containing renal calculi.

Side effects

a) *Common:* 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.

b) *Rare:* 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 fetoneonatal 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.

Use in children & adolescents

Use in children and adolescents is given in dose and administration.

Drug interaction

a) *With medicine:* A time-interval of 2 hours should be considered between this drug intake and 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 Bisphosphonates (diphosphonates) and Estramustine.

b) *With food & other:* Not applicable.

Overdose

In the event of over dosage symptomatic treatment should be given.

Storage

Store below 30°C. Protect from light. Keep all medicines out of the reach of children. Do not refrigerate or freeze.

Packing

Onvicon Plus Suspension: Each box contains a glass bottle of 200 ml suspension with a measuring cup.

Onvicon DX Suspension: Each box contains a glass bottle of 200 ml suspension with a measuring cup.



Manufactured by

ONE PHARMA LTD.

C-23-24, BSCIC I/A

Bogura, Bangladesh

LF0073

Rev.01
OVPD