

Apidone[®]

Domperidone

COMPOSITION:

Apidone 10 Tablet: Each tablet contains Domperidone 10 mg (as Domperidone Maleate BP).

Apidone Suspension: Each 5 ml contains Domperidone BP 5 mg.

PHARMACOLOGY:

Apidone is a Dopamine antagonist. Because it does not readily enter the central nervous system, its effects are confined to the periphery and acts principally at the receptor in the chemo receptor trigger zone.

INDICATION:

1. Stimulation of gut motility: Non-ulcer dyspepsia, Esophageal reflux, reflux esophagitis and gastritis, Diabetic gastroparesis, Functional dyspepsia, Speeding barium transit in 'follow-through' radiological studies.

2. Prevention and symptomatic relief of acute nausea and vomiting from any cause including cytotoxic therapy, radio therapy and anti-parkinsonism therapy. 3. In the treatment of migraine.

DOSE & ADMINISTRATION:

The recommended oral dose for Adults : 10 - 20 mg every 4 - 8 hours daily. Children: 0.2 - 0.4 mg/kg every 4 - 8 hours daily. Note: Apidone tablet and suspension should be taken 15 - 30 minutes before a meal. For acute nausea and vomiting, maximum period of treatment is 12 weeks.

CONTRA-INDICATION:

Domperidone is contraindicated to patients who have known hypersensitivity to this drug and in case of neonates.

WARNING AND PRECAUTION:

Domperidone should be used with absolute caution in case of children because there may be an increased risk of extra-pyramidal reactions in young children because of an incompletely developed blood-brain barrier.

SIDE EFFECTS:

Domperidone may produce hyperprolactinemia (1.3% frequency). This may result in galactorrhea, breast enlargement and soreness and reduced libido. Dry mouth (1.9%), thirst, headache (1.2%), nervousness, drowsiness (0.4%), diarrhea (0.2%), skin rash and itching (0.1%) may occur during treatment with Domperidone. Extra-pyramidal reactions are seen in 0.05% of patients in clinical studies.

USE IN PREGNANCY & LACTATION:

Pregnant women: The safety of Domperidone has not been proven and it is therefore not recommended during pregnancy. Animal studies have not demonstrated teratogenic effects on the fetus. Lactating mother: Domperidone may precipitate galactorrhea and improve post-natal lactation. It is secreted in breast milk but in very small quantities insufficient to be considered harmful.

USE IN CHILDREN & ADOLESCENTS:

Use in children under 2 years of age is contraindicated. Apidone tablet is not suitable for use in adolescents weighing less than 35 kg.

DRUG INTERACTION:

Domperidone may reduce the hypoprolactinemic effect of Bromocriptine. The action of Domperidone on GI function may be antagonized by anti-muscarinics and opioid analgesics.

OVERDOSE:

symptoms of overdose may include drowsiness, dizziness, confusion, twitching, muscle rigidity, and irregular heartbeat.

STORAGE:

Store in a dry and cool place below 30^o C temperature and keep away from light and moisture. Keep out of reach of children.

INFORMATION FOR THE PATIENT:

- 1) Shake well before using the suspension.
- 2) Do not discontinue the therapy suddenly, without consulting your doctor.
- 3) Discard unused portion of reconstituted suspension after the above mentioned time.

PACKING:

Apidone 10 Tablet: Each box contains 10x10's tablets in blister pack.

Apidone Suspension: Each bottle contains 60 ml of suspension with a measuring spoon.



Manufactured by

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