

**NAUZEX®**  
**10 mg Tablets**

**Dear patient,**

**Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.**

**Information about NAUZEX**

Each NAUZEX tablet for oral administration contains 10 mg domperidone.

Domperidone is a peripheral dopamine antagonist with antiemetic and gastroprokinetic properties.

Domperidone is effective in increasing gastro-intestinal motility. It does not alter gastric secretions.

Domperidone does not readily cross the blood-brain barrier and therefore is not expected to have central effects; Domperidone also stimulates release of prolactin from the pituitary gland.

NAUZEX® is indicated for the treatment of:

-Nausea and vomiting

-Hiccup

-Dyspeptic symptom complex that is associated with delayed gastric emptying, gastro-esophageal reflux and esophagitis

-Symptomatic management of upper gastrointestinal motility disorders associated with chronic and subacute gastritis and diabetic gastroparesis.

-To prevent gastrointestinal symptoms associated with the use of dopamine agonist antiparkinsonian agents.

**The way to take NAUZEX**

Take NAUZEX as directed by your doctor. Do not discontinue the treatment without consulting your physician.

The daily recommended dosage is to be taken 15 to 30 minutes before meals.

*For the treatment of acute conditions (mainly nausea, vomiting and hiccup):*

Adults: 20 mg (2 tablets) 3 to 4 times per day before meals and, if necessary, before retiring

Children: 10 mg (1 tablet) 3 to 4 times per day before meals and, if necessary, before retiring

*For the treatment of chronic conditions (mainly dyspepsia):*

Adults: 10 mg (1 tablet) taken 3 times per day before meals. The dosage may be doubled.

Children: 5 mg (half a tablet) 3 to 4 times per day before meals and, if necessary, before retiring.

**Duration of treatment**

The duration of treatment is determined according to the disease process.

**In case of overdose**

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

**In case of missed dose**

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

**Contraindications**

This drug is contraindicated in the following conditions:

-Known hypersensitivity to any of the components

-In the presence of gastro-intestinal hemorrhage, obstruction or perforation

-In patients with a prolactin-releasing pituitary tumor (prolactinoma).

**Precautions**

-This drug must be used with caution in patients with hepatic impairment and in the elderly; dosage should be decreased to half in patients with severe renal impairment.

-Inform your doctor before using this medication in case of pregnancy or lactation; domperidone is excreted in breast milk in very low concentrations.

**Associations with other medications**

Please inform your doctor if other medicines are being taken or have been taken recently. Concomitant use with ketoconazole is contra-indicated. Caution should be exercised with the azole antifungals, macrolide antibiotics, HIV protease inhibitors and nefazodone. Anticholinergic agents may antagonize the effect of domperidone. Domperidone suppresses the peripheral effects of dopaminergic agonists. Antacids and anti-secretory agents lower the oral absorption of domperidone.

**Adverse reactions**

This drug is usually well tolerated. Occasionally reported adverse effects were dry mouth, transient skin rash or itching, diarrhea and rarely abdominal cramps may occur. Reversible raised serum prolactin levels have been observed which may lead to galactorrhoea and gynaecomastia. Please inform your doctor if any side effect appears or becomes bothersome.

**Storage**

Store at controlled room temperature (up to 30°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

**Pack Presentation**

NAUZEX, Domperidone 10 mg, pack of 30 tablets

**Revision date: 03/2009**

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