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 with the following excipients: lactose monohydrate, corn starch, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, and colloidal silicon dioxide.
Domperidone is a dopamine antagonist with anti-emetic properties. Domperidone does not readily cross the blood-brain barrier. Its anti-emetic effect may be due to a combination of peripheral (gastrokinetic) effects and antagonism of dopamine receptors in the chemoreceptor trigger zone. It does not alter gastric secretions.
Domperidone also stimulates the release of prolactin from the pituitary gland.
NAUZEX is indicated for the relief of the symptoms of nausea and vomiting.
The way to take NAUZEX
Take NAUZEX as directed by your doctor. It is recommended to take NAUZEX tablets before meals.
This drug should be used at the lowest effective dose for the shortest duration necessary to control nausea and vomiting.
The recommended daily dose in adults and adolescents over 12 years of age and weighing 35 kg or more is 1 tablet up to 3 times daily with a maximum dose of 30 mg per day.
Duration of treatment
Usually, the maximum treatment duration should not exceed one week.
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
If you miss a dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.
Contraindications
This drug is contraindicated in the following conditions:
-Known hypersensitivity to any of the components
-Moderate or severe hepatic impairment
-In patients with a prolactin-releasing pituitary tumor (prolactinoma)
-In patients when gastric secretion could be harmful (e.g. gastro-intestinal hemorrhage, mechanical obstruction or perforation)
-In patients who have known existing prolongation of cardiac conduction intervals, particularly QTc, patients with significant electrolyte disturbances or underlying cardiac diseases such as congestive heart failure
-Co-administration with QT-prolonging drugs or potent CYP3A4 inhibitors
Precautions
-This drug may be associated with an increased risk of heart rhythm disorder and cardiac arrest. This risk may be more likely in those over 60 years old or taking doses higher than 30 mg per day. Seek medical attention immediately if you experience any of the following symptoms while taking this drug: palpitations, trouble breathing, and loss of consciousness.
-This drug should be used with caution in patients with renal impairment; the dosing frequency should be reduced to once or twice daily depending on the severity of the impairment, and the dose may need to be reduced. Patients on prolonged therapy should be reviewed regularly**.**

-Consult your doctor before using this medication in case of pregnancy or lactation.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

Concomitant use with medications known to prolong QTc interval or potent CYP3A4 inhibitors (protease inhibitors, systemic azole antifungals, some macrolides) is contra-indicated.

Concomitant use of moderate CYP3A4 inhibitors is not recommended.

Caution is needed with bradycardia and hypokalemia-inducing drugs, azithromycin, roxithromycin, and ketoconazole.

Adverse reactions

The most commonly reported adverse reaction is dry mouth.

Other reported adverse reactions include: allergic reactions, anxiety, agitation, nervousness, somnolence, headache, convulsion, extrapyramidal disorder, oculogyric crisis, disorders of the cardiovascular system, diarrhea, rash, pruritus, urticaria, angioedema, urinary retention, galactorrhea, breast pain, breast tenderness, gynecomastia, amenorrhea, asthenia, liver function test abnormal, and blood prolactin increased.

Inform your doctor if any adverse reaction 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: 11/2014

NAUT1/004

Manufactured by Mediphar Laboratories -Lebanon