Nausilex

tablet & ampoule

COMPANY NAME : Minapharm – Egypt
TRADE NAME : Nausilex ampoule & tablet
Generic Name : Alizapride HCl

COMPOSITION :
Nausilex tablets :
Each tablet contains :
Alizapride hydrochloride 55.8 mg equal to 50 mg of alizapride.

Nausilex ampoule :
Each ampoule contains :
Alizapride hydrochloride 55.8 mg equal to 50 mg of alizapride.
Excipients: Sodium Chloride, Water for injection.

PHARMACEUTICAL FORM :
Tablets & Solution for injection

PHARMACOLOGICAL ACTION :
The activity of alizapride is performed selectively, raising the sensitivity threshold of the vomiting center in the brainstem, this leads to a rapid decrease in nausea and vomiting caused by stimulation of the bulbar center.
Alizapride is therefore particularly active in clinical situations characterized by nausea and vomiting, in particular in nausea and vomiting with an organic or functional aetiology or caused by mitotic inhibitor therapy and surgery.
Alizapride does not affect cholinergic neurotransmission.

PHARMACOKINETICS :
Alizapride is highly absorbed. The half – life time is nearly 3 hours & the elimination is essentially through the urine unchanged. The cross of the drug through the placenta is very weak (0.004 %) in the rabbit. The cross through the blood–brain barrier is very weak and limited .The cross in the maternal milk is not known.

INDICATION:
Nausilex tablets:
It is suitable in the vomiting and nausea of various origins, including pre- and post-operative vomiting and nausea, with the exception of vomiting during pregnancy.

Nausilex solution for injection:
Particularly suitable for the treatment of vomiting and nausea associated with anti-cancer therapy.

DOSE :
Tablets: 2-4 tablets per day, unless different medical prescription.
Ampoules: Usually, 1-4 ampoules every 24 hours, unless different medical prescription.
- When treating nausea and vomiting caused by antineoplastic chemotherapy , the following dosage is recommended : 2 ampoules administered intravenously 20 –30 minutes before the start of treatment , followed by 1-2 ampoules administered intramuscularly 4-8 hours later .
-In the case of strongly emetic treatment , the daily dose can be increased up to 4 times , administering 4 ampoules intravenously 30 minutes before antineoplastic therapy , 4 ampoules intravenously together with antineoplastic therapy , and up to 8 ampoules intravenously or intramuscularly , at the rate of 2 ampoules every 4 hours , depending on the intensity and frequency of vomiting .
-The administration of one ampoule intramuscularly is recommended for the treatment of pre-operative nausea and vomiting.
-In post-operative vomiting, 1 ampoule 2-3 times a day by slow intravenous infusion or i.m.
Initial parentral treatment can be continued as maintenance therapy together with other pharmaceutical forms.

CONTRA-INDICATION:
*** Hypersensitivity to the active substance or to any of the excipients.**

*** Treatment must be avoided in patients with a previous history of delay dyskinetic reactions to neuroleptics.**
*** Patients with diagnosed or suspected pheochromocytoma : severe hypertensive crises have been reported in patients with pheochromocytoma treated with antidopaminergic drugs (including benzamides).**
*** Association with levodopa due to reciprocal antagonism.**
*** During pregnancy and lactation.**

SIDE EFFECTS :
The following undesirable effects have been reported, particulary with high dosages:
*** CNS and psychiatric disorders as extrapyramidal symptoms and these effects normally disappear spontaneously and completely with treatment withdrawal.**
Late persistent dyskinesia, in the event of prolonged treatment, especially in elderly patients, drowsiness, vertigo, headache , insomnia.
*** Gastrointestinal disorders as diarrhea, meteorism.**
*** Endocrine disorders as amenorrhea, galactorrhea , gynaecomastia ,hyperprolactinaemia**
*** General disorders as allergic reactions , including anaphylaxis.**
Vasomotor flushes have been reported after intravenous administration (increased sweating and / or sensation of skin burning) which were rapidly resolved. Patients must be informed of the minor nature of these symptoms which do not require special treatment .After the injection of Nausilex , asthenia and / or dryness of the faeces have been observed .
*** Cardiovascular disorders as orthostatic hypotension may be observed if high doses are used.**

DRUG DRUG INTERACTION :
*** Levodopa : reciprocal antagonism between levodopa and neuroleptic medications.**
*** Alcohol : enhances sedative effect of alizapride.**
*** Central nervous system sedatives : the sedative effects on the central nervous system and of alizapride are enhanced .**
*** Anticholinergics : concomitant administration may reduce the effects of alizapride.**
*** Digoxin : use with caution also in patients receiving simultaneous treatment with Digoxin , for whom digoxinemia control is recommended.**
*** Antihypertensives.**

PREGNANCY AND LACTATION :
In the absence of epidemiological studies, alizapride should not be prescribed during pregnancy. It is not known if alizapride hydrochloride is excreted into human milk and therefore its use during lactation is not recommended.

PRECAUTION :
- It is recommended that continuous treatment should not last longer than seven days.
- The dose should be reduced in the event of severe kidney failure.
- Patients are advised not to drink alcohol during treatment with alizapride.
- Alizapride is not recommended for epileptic patients because benzamides may lower the epileptic threshold. As in the case of other neuroleptic medications, Malignant Neuroleptic Syndrome (MNS) may occur, characterized by hyperthermia, extrapyramidal disorders, instability of the neurovegetative system, high CPK, therefore , this drug must be used with caution in the event of fever , one of the symptoms of MNS, and treatment must be suspended if MNS becomes apparent .

PACKAGE: Ampoules: Carton box contains 3 glass ampoules and inner leaflet.
Tablets: Carton box contains 2 strips each of 10 tablets and inner leaflet.

STORAGE: Ampoules: Store at temperature not exceeding 30°C.
Tablets: Store at temperature not exceeding 30°C in a dry place.

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