PATRIOT Pharmaceuticals Corp.

Levomepromazine

Nozinan®

Neuroleptic/Analgesic/Antiemetic

FORMULATION:
Each tablet contains :
Levomepromazine (as maleate)..... 25mg
Levomepromazine (as maleate)..... 100mg

INDICATIONS:
Levomepromazine (Nozinan) possesses anti-emetic, anti-histamine and anti-adrenaline activity and exhibits a strong sedative effect.

Levomepromazine potentiates the action of other central nervous system depressants but may be given in conjunction with appropriately modified doses of narcotic analgesics in the management of severe pain. It does not significantly depress respiration and is particularly useful where pulmonary reserve is low.

Levomepromazine is indicated in the management of terminal illness particularly in those marked by restlessness, anxiety, agitation, emotional disturbance, pain, nausea and vomiting.

Levomepromazine is indicated in psychiatry in schizophrenia especially when it is desirable to reduce psychomotor activity.

PHARMACOKINETICS:
Maximum serum concentrations are achieved in 2 – 3 hours. Excretion is slow, with half-life of about 30 minutes. It is eliminated via urine and feces.

CONTRAINDICATIONS:
Safety in pregnancy has not been established. There are no absolute contraindications to the use of Levomepromazine in terminal care.

The drug should be avoided or used with caution in patients with liver dysfunction or cardiac disease.

PRECAUTIONS:
The hypotensive effects of Levomepromazine should be taken into account when it is administered to patients with cardiac disease and the elderly or debilitated. Patients receiving large initial doses should be kept in bed.

Levomepromazine may cause drowsiness, disorientation, confusion or excessive hypotension, which may affect patient's ability to drive or operate machinery. Avoid alcoholic drinks.

ADVERSE EFFECTS:
Somnolence and asthenia are frequent side effects. Dry mouth is encountered occasionally. Hypotension may occur, especially in elderly patients. A raised ESR (*Erythrocyte Sedimentation Rate*) may occasionally be encountered. Agranulocytosis has been reported, as have photosensitivity and allergic skin reactions.

Parkinson-like reactions may occur in patients receiving prolonged high dosage. Jaundice is a rare side effect. Other adverse effects common to phenothiazine neuroleptics may be seen.

INTERACTIONS:
Simultaneous administration of desferrioxamine and prochlorperazine has been observed to induce a transient metabolic encephalopathy characterized by loss of consciousness for 48 – 72 hours. It is possible that this may occur with Levomepromazine since it shares many of the pharmacological activities of prochlorperazine. Adrenaline must not be used in patients overdosed with neuroleptics.

TOXICITY AND TREATMENT OF OVERDOSAGE:
Symptoms of Levomepromazine overdosage include drowsiness or loss of consciousness, hypotension, tachycardia, ECG changes, ventricular arrhythmias and hypothermia. Severe extra-pyramidal dyskinesias may occur.

If the patient is seen sufficiently soon (up to 6 hours) after ingestion of a toxic dose, gastric lavage may be attempted. Pharmacological induction of emesis is unlikely to be of any use. Activated charcoal should be given. There is no specific antidote. Treatment is supportive.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

DOSAGE AND ADMINISTRATION:
Adults: Ambulant patients – initially the total daily dose should not exceed 25-50mg, usually divided into 3 doses; a larger portion of the dosage may be taken at bedtime to minimize diurnal sedation. The dosage is then gradually increased to the most effective level compatible with sedation and other side effects.

Bed patients – Initially the total daily oral dosage may be 100 – 200mg, usually divided into 3 doses, gradually increased to 1 g daily if necessary. When the patient is stable, attempts should be made to reduce the dosage to an adequate maintenance level.

Children: Children are very susceptible to the hypotensive and soporific effects of Levomepromazine. It is advised that a total daily dose of 40 mg should not be exceeded. The average effective daily intake for a 10 year old is 15 – 20 mg.

Elderly patients – It is not advised to give Levomepromazine to ambulatory patients over 50 years of age unless risk of hypotensive reaction has been assessed.

AVAILABILITY: Nozinan 25mg tablets – Blister Pack x 10's (Box of 100's)
Nozinan 100mg tablets – Blister Pack of 10's (Box of 100's)

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

Registration Number: 25mg (DR-XY9226), 100mg (DR-9230)
Date of First Authorization: 25mg (July 1999), 100mg (October 1999)
Revision Date: 06/11/18

STORE AT TEMPERATURES NOT EXCEEDING 30°C

Manufactured for
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