

## IMPORTANT: PLEASE READ

### CONSUMER INFORMATION

PrNOZINAN<sup>®</sup>

#### Methotrimeprazine Hydrochloride Injection, USP

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Nozinan<sup>®</sup>. Contact your doctor or pharmacist if you have any questions about the drug.

#### ABOUT THIS MEDICATION

##### What the medication is used for:

Nozinan is used to treat psychotic disturbances, such as acute and chronic schizophrenia, psychosis in the elderly, and manic-depressive syndromes.

Nozinan may also be used to control pain due to various causes, to control nausea and vomiting or for the management of insomnia.

Ask your doctor if you have any questions about why Nozinan has been prescribed to you.

##### What it does:

Nozinan helps to:

- reduce and control psychotic symptoms,
- tranquilize,
- induce sleep,
- relieve pain.

##### When it should not be used:

Do not use Nozinan if you:

- are allergic to Nozinan, to phenothiazines (a type of antipsychotic) or to any of the ingredients in the product
- are in an altered state of consciousness or coma, due to alcohol, hypnotic drugs, or pain medications
- have liver disease
- have a blood disorder
- have a medical condition known as pheochromocytoma (a tumor of the adrenal gland)
- have a severe heart or blood vessel disorder
- have severely low blood pressure
- had brain damage
- have drowsiness, slow breathing, weak pulse
- Are going to receive anesthesia in the spine or for a region (such as an arm, leg or the lower part of your body)
- are at risk for urinary retention due to disorders of the urethra or prostate;
- are at risk of having glaucoma (increased pressure in the eye);

- have a history of agranulocytosis (low level of neutrocytes in your blood);
  - are taking medicines known as dopaminergics
- Nozinan is not indicated in elderly patients with dementia (mental decline) and is not recommended for use in patients with Parkinson's Disease.

##### What the medicinal ingredient is:

Methotrimeprazine hydrochloride.

##### What the nonmedicinal ingredients are:

0.1% ascorbic acid, 0.65% sodium chloride, 0.05% sodium sulfite and water for injection.

##### What dosage forms it comes in:

Solution for injection: 25 mg/mL

#### WARNINGS AND PRECAUTIONS

During the first few days of treatment, Nozinan may cause some people to become drowsy or less alert. You should not drive a car, operate machinery or participate in activities requiring alertness until you know how Nozinan affects you.

Muscular, neurologic, vascular, cardiac disorders, and hyperglycemia may occur in some patients taking Nozinan.

Nozinan is not recommended in pregnancy. In some cases, babies born to a mother taking Nozinan during pregnancy have experienced symptoms that are severe and require the newborn to be hospitalized. Sometimes, the symptoms may resolve on their own. Be prepared to seek immediate emergency medical attention for your newborn if they have difficulty breathing, are overly sleepy, have muscle stiffness, or floppy muscles (like a rag doll), are shaking, or are having difficulty feeding. Some babies born to mothers who are taking antipsychotic medicines have birth defects. It is important to talk to your doctor about the risks and benefits of taking Nozinan during pregnancy.

Effects on fertility: Nozinan may affect the fertility in both men and women.

##### **Before using Nozinan, tell your doctor or pharmacist if you:**

- have heart or blood vessel disease
- have a history of cerebrovascular disease including strokes or transient ischemic attacks (mini-strokes)
- suffer from an enlarged prostate (Benign Prostatic Hyperplasia)
- have or have had seizure disorders (e.g. epilepsy)
- have severe kidney problems
- have Parkinson's Disease
- have hypothyroidism (underactive thyroid gland)
- have cardiac failure (reduced functioning of heart muscles)

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- have myasthenia gravis (a disease that causes weakness in your muscles)
- plan to have surgery (or a procedure requiring anesthetics)
- are pregnant, are planning to become pregnant, or are of child-bearing potential and are not using effective contraception
- are breast-feeding

If you are given Nozinan and think that you may be exposed to extreme heat, or if you perform activities which may increase your body temperature (for example exercising vigorously or working in hot, sunny places) or if you are dehydrated, consult your doctor. Nozinan can affect the body's ability to regulate temperature.

If you experience severe constipation and you are elderly, please consult your doctor as soon as possible.

During long-term therapy, periodic liver function tests should be done.

### INTERACTIONS WITH THIS MEDICATION

The combination of Nozinan with some medicines can increase the quantity of other medicines in your body. This can lead to an increase in the risk of having side effects. Before using any prescription, over-the-counter medicines or herbal products, check with your doctor or your pharmacist.

#### Drugs that may interact with Nozinan include:

- Nozinan should not be used with drugs known as dopaminergics. If you are taking dopaminergics to treat your Parkinson's Disease, your doctor may slowly stop your treatment with dopaminergics before starting treatment with Nozinan.
- Nozinan is not recommended to be used with the following drugs:
  - drugs that prolong the QT interval (including certain antiarrhythmics, antidepressants and other antipsychotics)
  - drugs that cause electrolyte imbalance (including water pills, amphotericin B, corticosteroids and laxatives)
- Nozinan should be used with caution with the following drugs:
  - drug metabolized by the CYP2D6 enzyme system (including codeine, venlafaxine, amitriptyline and nortriptyline)
  - drugs that lower the seizure threshold, or lower blood pressure
  - guanethidine
  - atropine and atropine-like substances
  - lithium
- Nozinan may intensify the side effects (such as drowsiness) of the following drugs:

- allergy pills
- sleeping pills
- pain killers
- medications for seizure
- anti-depressant pills
- medications for mental illness

#### Drug - Lifestyle Interactions:

- Nozinan can add to the effects of alcohol. You should avoid consuming alcoholic beverages while on Nozinan therapy

Nozinan may cause a false reading of some types of pregnancy tests. For further information, please consult your doctor or your pharmacist.

### PROPER USE OF THIS MEDICATION

#### Usual dose:

Your doctor will decide the best dose for you based on your individual situation and needs. It is important to take Nozinan the way your doctor told you. Your doctor may increase or decrease your dose depending on your response.

You should remain lying down for at least one hour after your injection, because you may experience a decrease in blood pressure.

You may experience side effects if the drug is stopped suddenly. Contact your physician before stopping your drug.

#### For Adults

- Nozinan is given as an injection into the muscle. The number of times you receive an injection per day will depend on your condition.

#### For Children: the dose is based on the body weight

- Nozinan may be given as an injection into the muscle.
- Nozinan may also be given as a slow infusion in the vein that is diluted with a glucose solution.

#### Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

The signs that you have taken too much Nozinan may include drowsiness, spasm, shaking, seizure, low blood pressure, difficulty breathing and coma.

### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Nozinan, like any medication, may cause some side effects. Discuss with your doctor if you do experience side effects.

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Side effects include:

- drowsiness may appear early in treatment but usually disappears during the first weeks. If this effect persists, discuss this with your doctor. Your medication might have to be reduced.
- dryness of the mouth.
- in older patients, constipation and difficulty urinating.

Less common side effects include:

- weight gain has been occasionally reported in patients during long-term treatment with high doses.
- your skin may be more sensitive to sunlight.

Your doctor should check your body weight before starting Nozinan and continue to monitor it for as long as you are being treated.

Your doctor should take blood tests before starting Nozinan.

Your doctor will monitor your blood sugar, and your number of white blood cells. Should symptoms such as sore throat or fever appear, consult your doctor. Your doctor should continue to monitor your blood for as long as you are being treated.

If you have high levels of prolactin (measured with a blood test) and a condition called hypogonadism, you may be at increased risk of breaking a bone due to osteoporosis. This occurs in both men and women.

### SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

| Symptom / effect  | Talk with your doctor or pharmacist |              | Stop taking drug and seek immediate emergency assistance |
|---|-------------------------------------|--------------|--|
|   | Only if severe                      | In all cases |  |
| <b>Common</b>   |                                     |              |  |
| Low blood pressure with symptoms such as feeling dizzy, especially when getting up from a lying or sitting position |                                     | √            |  |
| <b>Uncommon</b>   |                                     |              |  |
| Allergic reactions, such as skin rash, redness or itching   |                                     |              | √  |
| Soreness of the mouth, gums or throat, abdominal pain or jaundice   |                                     |              | √  |
| Rapid or irregular heart beat, high or low blood pressure   |                                     |              | √  |

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|---|-------------------------------------|--------------|--|
|   | Only if severe                      | In all cases |  |
| Tremor, muscle stiffness, body spasm, impairment of voluntary movement, upward eye rolling, exaggeration of reflexes or drooling, convulsions and epileptic seizures. |                                     |              | √  |
| Hyperglycemia (too much sugar in the blood) with symptoms such as increased thirst, decreased appetite, nausea or vomiting  |                                     | √            |  |
| Respiratory infection, fever, flu-like symptoms, coughing, difficult or fast breathing  |                                     |              | √  |
| Increased sweating, confusion, reduced consciousness  |                                     |              | √  |
| Muscle twitching, uncontrolled movements of the mouth, tongue, face or jaw  |                                     |              | √  |
| Pain, swelling, redness or warmth in arms or legs, chest pain, anxiety, coughing up blood   |                                     |              | √  |
| Long-lasting (greater than 4 hours in duration) and painful erection of the penis   |                                     |              | √  |
| New or worsening constipation   |                                     | √            |  |
| Liver disease with symptoms such as abdominal pain, nausea, vomiting, loss of appetite, yellowing of the skin or eyes, dark urine, light-coloured stools.             |                                     | √            |  |
| <b>Unknown</b>  |                                     |              |  |
| Abdominal pain or discomfort and constipation, due to inactive intestinal muscles (paralytic ileus)   |                                     | √            |  |
| Reduced vision  |                                     | √            |  |
| Psychiatric disorders, such as indifference, anxiety reactions, or mood changes   |                                     | √            |  |
| Uncontrollable muscle contractions or spasms, causing abnormal fixed postures or twisting and repetitive movements  |                                     |              | √  |
| Restlessness, inability to stay still, fidgeting, pacing  |                                     |              | √  |

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|---|-------------------------------------|--------------|--|
|   | Only if severe                      | In all cases |  |
| Hyponatremia (low levels of sodium in your blood) with symptoms such as muscle weakness, spasms or cramps, nausea, vomiting, headache, confusion, fatigue |                                     | √            |  |

*This is not a complete list of side effects. For any unexpected effects while taking Nozinan, contact your doctor or pharmacist.*

### HOW TO STORE IT

Nozinan should be stored at room temperature (15°C to 30°C). Protect from exposure to light.

Keep out of reach and sight of children.

#### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### MORE INFORMATION

Your physician, nurse and pharmacist are always your best source of information about your condition and treatment. If you have additional questions or concerns, be sure to ask them.

Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by

visiting the Health Canada website (<https://www.canada.ca/en/health-canada.html>); the manufacturer's website [www.sanofi.ca](http://www.sanofi.ca), or by calling 1-800-265-7927.

This leaflet was prepared by sanofi-aventis Canada Inc.

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