

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrNOZINAN®

Methotrimeprazine Hydrochloride Injection, USP

Read this carefully before you start taking **NOZINAN** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **NOZINAN**.

Serious Warnings and Precautions

Drugs like NOZINAN can raise the risk of death in elderly people who have dementia. NOZINAN is not to be used in patients with dementia.

What is NOZINAN used for?

NOZINAN is used to:

- treat mental health problems that cause abnormal thinking and perception including schizophrenia, psychosis in the elderly and manic depressive syndromes
- control pain from various causes such as cancer, shingles, pain in the nerves of the face or ribs, and muscle pain
- treat nausea and vomiting
- manage insomnia

How does NOZINAN work?

Exactly how NOZINAN works is unknown, however it possesses properties that:

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

What are the ingredients in NOZINAN?

Medicinal ingredients: methotrimeprazine (as hydrochloride)

Non-medicinal ingredients: ascorbic acid, sodium chloride, sodium sulfite and water for injection.

NOZINAN comes in the following dosage forms:

Solution for injection: 25 mg/mL

Do not use NOZINAN if:

- you/your child are allergic to methotrimeprazine, phenothiazines (a type of antipsychotic) or to any of the other ingredients in NOZINAN
- you/your child are taking other drugs used to treat psychotic disorders including dopaminergics

- you/your child are in an altered state of consciousness or coma, due to alcohol, drugs that make you sleepy (hypnotic drugs), or pain medications
- you/your child have liver problems
- you/your child have a blood disorder
- you/your child have a condition called bone marrow depression
- you/your child have a medical condition known as pheochromocytoma (a tumor of the adrenal gland)
- you/your child have a severe heart or blood vessel disorder
- you/your child have severely low blood pressure
- you/your child have brain damage
- you/your child are going to receive anesthesia in the spine or for a large area of the body (such as an arm, leg or the lower part of your body)
- you/your child have a medical condition called myasthenia gravis (muscle weakness and fatigue)
- you/your child have urethra or prostate problems that may impact your/their ability to completely empty your/their bladder (urinary retention)
- you/your child are at risk for having glaucoma (increased pressure in the eye)

NOZINAN is not for use in children less than 1 year of age.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you/your child take NOZINAN. Talk about any health conditions or problems you may have, including if you/your child:

- have a heart or blood vessel disease
- have a history of having strokes
- are at risk for developing blood clots or having a stroke. Risk factors include:
 - a family history of blood clots or strokes
 - having diabetes
 - having high cholesterol
 - being over the age of 65
 - smoking
 - being overweight
 - taking oral birth control
 - not being able to move due to air travel or other reasons
- suffer from an enlarged prostate (Benign Prostatic Hyperplasia)
- have or have had seizure disorders (epilepsy)
- have kidney problems
- have Parkinson's disease
- have hypothyroidism (underactive thyroid gland)
- have heart failure (heart does not pump blood as well as it should)
- plan to have surgery
- are pregnant, are planning to become pregnant, or are of child-bearing potential and are not using effective contraception
- are breast-feeding or are planning to breastfeed. NOZINAN passes into the breastmilk. You should not breastfeed if you are taking NOZINAN
- are 65 years of age or older
- have heart problems or problems with your heart beat

- have low levels of potassium in the blood
- are taking any medications that affect how your heart beats

Other warnings you should know about:

Do NOT stop taking NOZINAN without talking to your healthcare professional first, as it may cause unwanted side effects such as headache, insomnia, numbness, tingling, burning, or prickling, nervousness, anxiety, nausea, sweating, dizziness, jitteriness and weakness.

Driving and Using Machines: Until you know how NOZINAN affects you, do not drive or use machinery, especially when you first start treatment. Taking NOZINAN can cause side effects such as:

- drowsiness
- dizziness, and
- blurred vision.

Effects on Newborns: In some cases, babies born to a mother taking NOZINAN during pregnancy have symptoms that are severe that require the newborn to be hospitalized. Sometimes, the symptoms may resolve on their own. You should be ready to get emergency medical help for your newborn if they:

- have trouble breathing
- are overly sleepy
- have muscle stiffness or floppy muscles (like a ragdoll)
- are shaking or
- have difficulty feeding

Increased levels of prolactin: NOZINAN can raise the levels of a hormone called “prolactin”. If you have high levels of prolactin and a condition called hypogonadism, you may be at an increased risk of breaking a bone due to osteoporosis. This occurs in both men and women. High levels of prolactin may also impair fertility in both men and women.

Dehydration and Overheating: It is important to not become too hot or dehydrated while you are taking NOZINAN.

- Do not exercise too much
- In hot weather, stay inside in a cool place if possible
- Stay out of the sun
- Do not wear too much clothing or heavy clothing
- Drink plenty of water

Monitoring and laboratory tests: Your healthcare professional should do tests before starting treatment with NOZINAN and while you are taking it. These tests will monitor:

- blood sugar,
- body weight,
- blood count,
- liver and kidney,
- blood pressure, and
- if you/your child develop a sore throat, fever and weakness

Sensitivity to sunlight: NOZINAN may increase sensitivity to sunlight. You/your child should wear sunscreen if you/they will be spending time outside.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interaction

NOZINAN should not be used if you are taking dopaminergics which are used to treat Parkinson's disease.

The following may interact with NOZINAN:

- alcohol. You should avoid drinking alcohol while on NOZINAN.
- drugs used to treat mental and emotional disorders called phenothiazines
- drugs used to treat allergies
- drugs used to treat insomnia, anxiety, panic attacks and seizures
- drugs used to relieve pain such as narcotics, analgesics and amitriptylinoxide
- drugs used manage psychosis
- drugs used to treat heart rhythm problems such as atropine
- drugs that cause electrolyte imbalance such as water pills, amphotericin B, corticosteroids and laxatives
- drugs used to treat depression such as monoamine oxidase inhibitors and amitriptyline
- drugs that lower the seizure threshold
- drugs used to treat gastrointestinal disorders such as magnesium, aluminum and calcium salts, oxides and hydroxides
- drugs used to treat diabetes
- drugs used lower blood pressure, such as guanethidine
- drug used to treat mental health problems called lithium

NOZINAN may cause a false reading of some types of pregnancy tests. For more information, talk to your healthcare professional.

How to take NOZINAN:

- NOZINAN will be given to you/your child by a healthcare professional.
- For adults, the solution of NOZINAN will be given 3 or 4 times a day through a needle placed in a large muscle. This is called intramuscular (IM) injection.
- For children, the solution of NOZINAN is given 1 or more times a day as an IM injection or as an infusion into the vein. This is called intravenous infusion.
- After you/your child have been given NOZINAN, you/your child should remain lying down for at least one hour.

Usual dose:

The usual dose of NOZINAN will be different for everyone. Your/your child's healthcare professional will decide on the dose that is right for you/your child. Your/your child's dose will depend on age, weight and other conditions or illnesses you/your child have.

Overdose:

The signs of an overdose may include drowsiness, spasm, shaking, seizure, low blood pressure, difficulty breathing and coma.

If you think you, or a person you are caring for, have taken too much NOZINAN, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you/your child miss a dose, take it as soon as possible. If it is almost time for the next dose, skip the missed dose and take your next dose at the regular time. Do not take 2 doses at once.

What are possible side effects from using NOZINAN?

These are not all the possible side effects you may have when taking NOZINAN. If you experience any side effects not listed here, tell your healthcare professional.

Side effects include:

- drowsiness
- dryness of the mouth
- constipation and difficulty urinating
- weight gain
- skin may be more sensitive to sunlight

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up)		√	
UNCOMMON			
Allergic Reaction: difficulty swallowing or breathing, wheezing, drop in blood pressure, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat			√
Oropharyngeal disorder: soreness of the mouth, gums or throat.			√
Heart rhythm problems: dizziness, light headedness, shortness of			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
breath, racing heart, palpitations (sensation of rapid, pounding, or irregular heart beat), fainting, or seizures			
Extrapyramidal reactions: tremor, muscle stiffness, body spasm, impairment of voluntary movement, upward eye rolling, exaggeration of reflexes or drooling			√
Hyperglycemia (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue		√	
Respiratory Depression (also known as hypoventilation): slow, shallow or weak breathing; blue lips, fingers, toes; confusion; headaches			√
Seizures (fit): uncontrollable shaking with or without loss of consciousness		√	
Tardive Dyskinesia: muscle twitching or unusual/abnormal movement of the face or tongue or other parts of your body			√
Thromboembolism (blood clot in a vein or artery): pain or tenderness or swelling in your arm or leg, skin that is red or warm, coldness, tingling or numbness, pale skin, muscle pain or spasms, weakness			√
Priapism: long-lasting (greater than 4 hours in duration) and painful erection of the penis			√
New or worsening constipation		√	
Liver Injury: pain in the right abdomen, fever, fatigue, weakness, nausea, vomiting, loss of appetite, yellowing of the skin or eyes, dark urine		√	
UNKNOWN			

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Paralytic Ileus: abdominal pain or discomfort and constipation, due to inactive intestinal muscles		√	
Reduced vision		√	
Behavior and mood changes: indifference, anxiety, anger		√	
Dystonia: twisting movements that you cannot control and can affect posture or the face including eyes, mouth, tongue or jaw, tightness of the throat, difficulty swallowing or breathing which may lead to choking			√
Akathisia: restlessness, inability to stay still, fidgeting, pacing			√
Hyponatremia (low sodium in the blood): lethargy, confusion, muscular twitching, achy, stiff or uncoordinated muscles, seizure, coma		√	
Neuroleptic Malignant Syndrome: pronounced muscle stiffness or inflexibility with high fever, rapid or irregular heartbeat, sweating, state of confusion or reduced consciousness			√
Agranulocytosis (decrease in white blood cells): frequent infection with fever, chills, sore throat			√
Neutropenia (decreased white blood cells): infections, fatigue, fever, aches, pains and flu-like symptoms			√
Hyperprolactinemia (elevated prolactin levels): irregular menstrual cycles, production and discharge of breast milk, abnormal hair growth, infertility			√
Feeling very hot and unable to cool down (generally as a result of several factor together, such as vigorous exercise, dehydration, warm conditions)		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Necrotising colitis: (serious disease that affects the intestines): swelling or bloating in the abdomen, discolouration of the abdomen, bloody stool, diarrhea, vomiting			√
SIADH—syndrome of inappropriate antidiuretic hormone secretion: concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits (seizures) which may be due to inappropriate secretion of ADH (antidiuretic hormone).			√
Torsade de pointes (life-threatening irregular heartbeat)			√
Thrombocytopenia (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness			√
Eosinophilia (increased numbers of certain white blood cells): abdominal pain, rash, weight loss, wheezing.		√	
Hyperthermia (very high body temperature): severe muscle spasms, fast heart rate		√	
Gynecomastia: breast enlargement in men (and /or women)			√
Vaginal bleeding changes: increased or decreased menstrual bleeding, spotting, infrequent periods or absence of bleeding			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

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.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.

Storage:

Store NOZINAN at room temperature (15°C to 30°C). Protect from light.

Keep out of reach and sight of children.

If you want more information about NOZINAN:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.sanofi.ca, or by calling 1-800-265-7927.

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