

# Nozinan<sup>®</sup> Tablets

*methotrimeprazine maleate*

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## Consumer Medicine Information (CMI)

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### What is in this leaflet

This leaflet answers some common questions about Nozinan.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits he expects it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

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### What Nozinan is used for

Nozinan is a type of neuroleptic used in both psychiatry and severe pain.

It is not known exactly how Nozinan has these effects.

The effect of Nozinan is to relieve severe pain without it making you feel sick or vomiting. It relieves the anxiety and distress associated with severe pain. Nozinan can also be used to treat schizophrenia.

Your doctor, however, may prescribe Nozinan for another purpose.

**Ask your doctor if you have any questions about why it has been prescribed for you.**

This medicine is only available with a doctor's prescription.

There is no evidence that this medicine is addictive.

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### Before you take it

#### ***When you must not take it***

**Do not take Nozinan if you have:**

- liver disease
- heart disease

**Do not take Nozinan if you are allergic to it or any of the ingredients listed at the end of this leaflet.**

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

**Do not take it if you are pregnant or intend to become pregnant.**

It may affect your developing baby if you take it during pregnancy.

**Do not take it if you are breastfeeding or planning to breastfeed.**

Nozinan may pass into breast milk and there is a possibility your baby may be affected.

**Do not take it after the expiry date (EXP) printed on the pack.**

If you take it after the expiry date has passed, it may not work as well.

**Do not take it if the packaging is damaged or shows signs of tampering.**

#### ***Before you start to take it***

**Tell your doctor or pharmacist if you have allergies to:**

**any of the ingredients listed at the end of this leaflet  
any other substances, such as  
foods, preservatives or dyes.**

**Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.**

Like most medicines of this kind, Nozinan is not recommended to be used during pregnancy. Your doctor or pharmacist will discuss the risks and benefits of taking it if you are pregnant.

**Tell your doctor or pharmacist if you are breastfeeding or planning to breastfeed.**

It is not known whether Nozinan passes into breast milk. Your doctor or pharmacist will discuss the risks and benefits of taking it if you are breastfeeding or planning to breastfeed.

**Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:**

- heart disease
- liver disease
- slow or irregular heartbeats or palpitations or have a family history of these
- low levels of potassium, calcium or magnesium in your blood
- blood clots
- if you are unable, or find it difficult, to eat
- dementia
- if you have a high consumption of alcohol

**Tell your doctor or pharmacist if you plan to have surgery.**

**If you have not told your doctor or pharmacist about any of the above, tell them before you take Nozinan.**

#### ***Taking other medicines***

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from**

your pharmacy, supermarket or health food store.

Some medicines may interfere with the absorption of Nozinan. These include:

- sedatives (medicines that help you sleep)
- hypnotics (medicines that help you relax or reduce stress)
- alcohol
- desferrioxamine (removes excess iron from the body)
- adrenaline (sends more oxygen to the brain and muscles)

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Nozinan.

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## How to take it

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### *How much to take*

The standard dose for this medicine is half to two Nozinan 25 mg tablets every 4 to 8 hours.

Your doctor may have prescribed a different dose.

**Ask your doctor or pharmacist if you are unsure of the correct dose for you.**

They will tell you exactly how much to take.

**Follow the instructions they give you.**

If you take the wrong dose, Nozinan may not work as well and your problem may not improve.

### *How to take it*

**Swallow the tablets whole with a full glass of water or other liquid.**

### *When to take it*

**Take Nozinan tablets every 4 to 8 hours irrespective of meals, or as prescribed by your doctor.**

**If you are not sure when to take it, ask your doctor or pharmacist.**

### *How long to take it*

**Continue taking the tablets until your doctor tells you to stop.**

**Ask your doctor or pharmacist if you are not sure how long to take the medicine for.**

### *If you forget to take it*

**Do not try to make up for missed doses by taking more than one dose at a time.**

This may increase the chance of getting an unwanted side effect.

**If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.**

**Do not take a double dose to make up for the dose you have missed.**

**If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.**

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering when to take your medicine, ask your pharmacist for hints.**

### *If you take too much (overdose)*

**Immediately telephone your doctor, or the Poisons Information Centre (New Zealand 0800 POISON or 0800 764766), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Nozinan.**

**Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

If you take too many Nozinan tablets, you will probably feel very sleepy or dizzy, you may faint or your heartbeat may become irregular.

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## While you are taking it

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### *Things you must do*

**Tell all the doctors, dentists and pharmacists who are treating you that you are taking Nozinan.**

**If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Nozinan.**

**If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.**

### *Things you must not do*

**Do not take more than the recommended dose unless your doctor tells you to.**

**Do not give this medicine to anyone else, even if they have the same condition as you.**

**Do not use this medicine to treat any other complaints unless your doctor tells you to.**

**Do not stop taking Nozinan, or lower the dosage, without checking with your doctor.**

Your doctor may want you to gradually reduce the amount you are using before stopping completely.

**Do not stop taking your tablets because you are feeling better, unless advised by your doctor.**

### *Things to be careful of*

**If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up.**

**Be careful driving or operating machinery until you know how Nozinan affects you.**

It may cause dizziness or light-headedness in some people, especially after the first dose. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you feel dizzy.

**Be careful if you are over 65 and unwell or taking other medicines.** Some people may experience side effects such as drowsiness, confusion, dizziness and

unsteadiness, which may increase the risk of a fall.

**The effects of alcohol could be made worse while taking Nozinan. It is recommended that you do not drink alcohol while taking Nozinan**

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## Side effects

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All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits he expects it will have for you.

**Do not be alarmed by this list of possible side effects.** You may not experience any of them.

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Nozinan.** It helps most people with severe pain or schizophrenia, but it may have unwanted side effects in a few people.

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- drowsiness
- weakness
- dry mouth

These are mild side effects of this medicine and usually short-lived.

**Tell your doctor or pharmacist immediately if you notice any of the following:**

- **dizziness, feeling faint or loss of alertness**
- **skin irritation or rash especially after going out into the sun, which may result in burning**
- **fever, ulcers in the mouth or throat or a sore throat**
- **tremors or shaking, muscle stiffness**
- **constipation, which may become severe and stop food moving through the bowel**
- **unwanted or persistent erections**

**Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:**

- **high temperature, sweating, pale complexion, difficulty in passing urine**
- **colicky stomach pain with bloody diarrhoea**

These may be serious side effects of Nozinan. You may need urgent medical attention. Serious side effects are uncommon.

**If any of the following happen, stop taking this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:**

- **swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.**
- **hives**
- **fainting**
- **yellowing of the skin and eyes (jaundice)**

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Nozinan. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

**Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.**

Other side effects not listed above may occur in some consumers.

**Do not be alarmed by this list of possible side effects.** You may not experience any of them.

**Ask your doctor or pharmacist to answer any questions you may have.**

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## After taking it

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**If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.**

## Storage

**Keep your tablets in the blister pack, inside the box in which they came until it is time to take them.**

If you take the tablets out of the box or the blister pack they may not keep well.

**Keep the medicine in a cool, dry place where the temperature stays below 25°C.**

**Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill.**

**Do not leave it in the car.**

Heat and damp can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

## Disposal

**If your doctor or pharmacist tells you to stop taking Nozinan, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.**

**Return any unused medicine to your pharmacist.**

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## Product description

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### *What it looks like*

Nozinan comes in two types of tablets:

Nozinan 25 mg - white, rounded faced, round, breakable tablet, marked "L 25"

Nozinan 100 mg - white, rounded faced, round, breakable tablet, marked "L 100".

The 25 mg strength is available in boxes of 100 tablets.

The 100 mg strength is available in boxes of 100 tablets.

### *Ingredients*

Active Ingredient:

Nozinan 25 mg – 25 mg methotrimeprazine maleate per tablet

Nozinan 100 mg – 100 mg  
methotrimeprazine maleate per  
tablet.

Inactive Ingredients:

The 25 mg tablets also contain:

- potato starch
- calcium hydrogen phosphate
- sodium lauryl sulfate
- magnesium stearate
- purified water
- polyvinyl acetate
- macrogol 6000.

The 100 mg tablets also contain:

- potato starch
- calcium carbonate
- sodium lauryl sulfate
- stearic acid
- purified water
- polyvinyl acetate
- macrogol 6000.

Nozinan does not contain gluten,  
sucrose, lactose, tartrazine or any  
other azo dyes.

### ***Manufacturer/Sponsor***

Nozinan is made in Portugal.

sanofi –aventis new zealand limited  
Level 8, James and Wells Tower  
56 Cawley Street  
Ellerslie  
Auckland

This leaflet was prepared in February  
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