

Tramadol AN

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I being given Tramadol AN?

Tramadol AN is used to relieve severe pain and belongs to a group of medicines called analgesics (pain relievers). For more information, see Section [1. Why am I being given Tramadol AN?](#) in the full CMI.

2. What should I know before I am given Tramadol AN?

Do not use if you have ever had an allergic reaction to tramadol or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given Tramadol AN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Tramadol AN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How will I be given Tramadol AN?

Tramadol AN injection is given into a vein or muscle. Your doctor will decide how you will receive Tramadol AN, what dose and for how long. If you have been prescribed Tramadol AN injections, your doctor or nurse will administer them for you.

More instructions can be found in Section [4. How will I be given Tramadol AN?](#) in the full CMI.

5. What should I know while using Tramadol AN?

Things you should do	<ul style="list-style-type: none">• Tell any other doctors, dentists and pharmacists who treat you that you are using Tramadol AN.• If you are going to have surgery, tell the surgeon or anaesthetist that you are using Tramadol AN. It may affect other medicines used during surgery.• If your pain lessens or gets worse, consult your doctor.• If you become pregnant while you are being treated with Tramadol AN, tell your doctor immediately.• If you are to have any tests, tell your doctor that you are using Tramadol AN. It may affect the results of some tests.
Things you should not do	<ul style="list-style-type: none">• Do not give Tramadol AN to anyone else, even if they have the same condition as you.• Do not use Tramadol AN to treat any other complaints unless your doctor tells you to.• Do not stop taking Tramadol AN or change the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how Tramadol AN affects you.• This medicine may cause dizziness, light-headedness, tiredness, drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.
Drinking Alcohol	<ul style="list-style-type: none">• Do not drink alcohol while you are being treated with Tramadol AN.• Alcohol may increase your risk of serious side effects while being treated with Tramadol AN.

For more information, see Section [5. What should I know while using Tramadol AN?](#) in the full CMI.

6. Are there any side effects?

The most common side effects include dizziness, sedation, fatigue, headache, constipation, nausea or vomiting, sweating, dry mouth. If you experience severe side effects such as skin disorders, swelling, chest tightness/wheezing, heart palpitations, faintness, hallucinations or convulsions, urgent medical attention may be required.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING

Limitations of use

Tramadol AN should only be used when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

Hazardous and harmful use

Tramadol AN poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

Life threatening respiratory depression

Tramadol AN can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing) even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting treatment and after a dose increase, if you are older, or have existing problems with your lungs. Your doctor will monitor you and change the dose as appropriate.

Use of other medicines while using Tramadol AN

Using Tramadol AN with other medicines that can make you feel drowsy, such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol, may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using Tramadol AN.

Tramadol AN

Active ingredient: *Tramadol hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Tramadol AN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Tramadol AN.**

Where to find information in this leaflet:

- [1. Why am I being given Tramadol AN?](#)
- [2. What should I know before I am given Tramadol AN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given Tramadol AN?](#)
- [5. What should I know while using Tramadol AN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given Tramadol AN?

Tramadol AN contains the active ingredient tramadol hydrochloride

Tramadol AN is used to relieve severe pain and belongs to a group of medicines called opioid analgesics (pain relievers).

Tramadol AN is for use in adults and children over 12 years of age. It should not be used in children under the age of 12 years or following the removal of tonsils and/or adenoids in people between 12 and 18 years.

Your doctor may have prescribed Tramadol AN for another reason. Ask your doctor why Tramadol AN has been prescribed for you.

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

2. What should I know before I am given Tramadol AN?

Warnings

Do not use Tramadol AN if:

- you have a known allergy to tramadol or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include skin rash, itching, difficulty breathing and swelling of the face (including lips, tongue, throat etc.)
- you have an allergy to any other medicines known as opioid analgesics, e.g. morphine or codeine
- you have respiratory disease or slow or shallow breathing
- you have taken large amounts of alcohol or other substances which can affect your level of consciousness. Some examples of these substances include sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions)
- you are taking medicine for depression containing a "monoamine oxidase inhibitor", also known as a MAOI, or have taken one within the past two weeks. Examples of MAOI-containing medicines are Nardil® and Parnate®.
- you have uncontrolled epilepsy or if your epilepsy is not well controlled by treatment
- you are younger than 12 years old or if you are between 12 – 18 years of age and are recovering from an operation to remove your tonsils and/or adenoids.

Addiction

You can become addicted to Tramadol AN even if you take it exactly as prescribed. Tramadol AN may become habit forming causing mental and physical dependence. If abused, it may become less able to reduce pain.

Dependence

As with all other opioid containing products, your body may become used to you receiving Tramadol AN. Using it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop using Tramadol AN suddenly, so it is important to use it exactly as directed by your doctor.

Tolerance

Tolerance to Tramadol AN may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

Withdrawal

Continue using your medicine for as long as your doctor tells you. If you stop having this medicine suddenly, your pain may worsen, and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate or pupil size.
- watery eyes, runny nose, chills or yawning
- increased sweating.

Very rarely, some patients have experienced the following withdrawal reactions:

- panic attacks
- severe anxiety
- hallucinations
- tingling or numbness (pins and needles)
- ringing in your ears
- confusion, delusions or paranoia.

You must tell your doctor if you:

- have a known allergy to tramadol or any of the ingredients listed at the end of this leaflet
- are known to be sensitive to opioids
- drink alcohol
- have or ever had any other health problems, including:
 - any lung or breathing problems
 - sleep-related breathing disorders
 - any diseases of the kidney, liver, biliary tract or pancreas
 - any stomach problems
 - a serious head injury
 - any fits or convulsions/epilepsy
- have or have had any problems with drug or alcohol dependence.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them.

See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tramadol AN is not recommended for use during pregnancy. Tramadol can pass to your unborn baby when you are pregnant. Talk to your doctor about the risks and benefits of using Tramadol AN during pregnancy.

Tell your doctor if you are breast-feeding or plan to breast-feed. Tramadol AN is not recommended for use during breast-feeding. Talk to your doctor about the risks and benefits of using Tramadol AN when breast-feeding.

Children

Tramadol AN is for use in adults and children over 12 years of age. It should not be used in children under the age of 12 years or following the removal of tonsils and/or adenoids in people under 18

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Tramadol AN. These include:

- carbamazepine (e.g. Tegretol®)
- coumarin derivatives (e.g. warfarin: Some Brand names are Coumadin®, or Marevan®)
- medicines for irregular or rapid heart beat (e.g. quinidine)
- medicines for depression, sleeplessness or mental conditions such as selective serotonin reuptake inhibitors (SSRI's), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants, mirtazapine, bupropion, tetrahydrocannabinol, phenothiazines or antipsychotics
- some antibiotics
- a group of medicines called anticholinergics. These medicines can be used to treat a wide range of medical conditions including asthma, a respiratory condition called chronic obstructive pulmonary disorder (COPD), Parkinson's Disease, cardiovascular disease, urinary incontinence (loss of bladder control), psychiatric disorders including schizophrenia, anxiety, depression, allergies and travel sickness/nausea.

These medicines may be affected by Tramadol AN or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Tramadol AN.

4. How will I be given Tramadol AN?

Tramadol AN injection is given into a vein or muscle. Your doctor will decide:

- how you will receive Tramadol AN

- what dose you will receive
- for how long you will receive it for.

If you have been prescribed Tramadol AN injections, your doctor or nurse will administer them for you.

If you are given too much Tramadol AN

As Tramadol AN is usually given to you under the supervision of your doctor, it is very unlikely that you will be given too much of the medicine. Your doctor, nurse or pharmacist will be monitoring your progress and checking the medicine that you are given.

If you think that you have been given too much Tramadol AN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Tramadol AN?

Things you should do

- If you become pregnant while you are being treated with Tramadol AN, tell your doctor immediately.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Tramadol AN.
- If your pain is not severe and you feel that you do not need as much Tramadol AN as your doctor ordered, consult your doctor.
- Tell your doctor if your pain is not helped or gets worse.
- Tell any other doctors, dentists, and pharmacists who treat you, that you are taking this medicine.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.
- If you have to have any tests tell your doctor you are being given Tramadol AN. Tramadol AN may affect the results of some tests.
- Keep all of your doctor's appointments so that your progress can be checked.

Things you should not do

Do not give Tramadol AN to anyone else, even if they have the same condition as you.

Do not use Tramadol AN to treat any other complaints unless your doctor tells you to.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Tramadol AN affects you.

This medicine may cause dizziness, light-headedness, tiredness, drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous

Drinking alcohol

Tell your doctor if you drink alcohol.

You must not drink alcohol while using Tramadol AN.

Looking after your medicine

If you are being given Tramadol AN while in hospital, it will be stored in the pharmacy or on the ward.

It should be kept in a cool dry place away from moisture, heat or sunlight below 30°C and out of reach of children. It should not be stored:

- in the bathroom or near a sink, or
- in the car or on window sills.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to the pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • dizziness • sedation, fatigue • headache • constipation • nausea or vomiting • sweating • dry mouth • indigestion • hiccups • changes in appetite 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • skin rash (red spots or patches), itching, hives, skin lumps • swelling or puffiness of the eyelids, face or lips • chest tightness, wheezing or pain in the chest • heart palpitations, faintness or collapse • muscle weakness • tremor 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest</p>

<ul style="list-style-type: none"> • seizures (fits) • hallucinations • respiratory depression • changes in mood • confusion • sleep disturbance • blurred vision • difficulty in passing urine • low blood glucose (hypoglycaemia) • Serotonin Syndrome: signs of this vary and are not specific: they may include fever, sweating, confusion, agitation, diarrhoea, muscle twitching, spontaneous muscle contraction, tremor, difficulty with walking and balance. Serotonin Syndrome may result from interaction of tramadol with other medicines which increase serotonin effects, for example, the SSRI antidepressants. • Severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system. • Androgen deficiency symptoms such as loss of libido, impotence (erectile dysfunction) or your menstrual cycle stops. • Extreme fatigue, lack of appetite, weight loss, severe abdominal pain, nausea, vomiting or low blood pressure. This may indicate that you have adrenal insufficiency (low cortisol levels). 	<p>hospital if you notice any of these serious side effects.</p>
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Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Tramadol AN contains

Active ingredient (main ingredient)	Tramadol hydrochloride
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • sodium acetate • water for injections

Tramadol AN does not contain any preservatives or bacteriostatic agents.

Do not take this medicine if you are allergic to any of these ingredients.

What Tramadol AN looks like

Tramadol AN is supplied in a 2mL glass ampoule containing a clear, colourless to slightly yellow coloured solution.

Tramadol AN is supplied as:

Tramadol AN tramadol hydrochloride 100 mg/2 mg solution for injection ampoule.
(AUST R 202840)

Who distributes Tramadol AN

Juno Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121
www.junopharm.com.au

Talk to your doctor if you experience any of the following symptoms while you are receiving Tramadol AN:

Extreme fatigue, lack of appetite, severe abdominal pain, nausea, vomiting or low blood pressure. This may indicate that you have adrenal insufficiency (low cortisol levels). Adrenal insufficiency is caused by failure of the adrenal glands to produce enough or any of the hormones cortisol and aldosterone.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

This leaflet was prepared in December 2025