

TRAMADOL AN INJECTION

Tramadol hydrochloride

Consumer Medicine Information

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.

What is in this leaflet

This leaflet answers some common questions about TRAMADOL AN. 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 TRAMADOL AN against the benefits this medicine is expected to have for you.

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

Keep this leaflet. You may need to read it again.

What TRAMADOL AN is used for

TRAMADOL AN is used to relieve severe pain and belongs to a group

of medicines called analgesics (pain relievers).

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.

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

Before you are given TRAMADOL AN

When you must not use it

TRAMADOL AN should not be given to you 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, eg. 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.

TRAMADOL AN should not be given to you after the expiry date printed on the pack.

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

TRAMADOL AN should not be used if the packaging is torn or shows signs of tampering.

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.

TRAMADOL AN given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

If you are not sure whether you should be given TRAMADOL AN, talk to your doctor.

Before you are given it

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
- you are known to be sensitive to opioids.
- you drink alcohol
- you have or ever had any other health problems, including:
 - any lung or breathing problems
 - sleep-related breathing disorders
 - any diseases of the kidney, liver or pancreas
 - any stomach problems
 - a serious head injury
 - any fits or convulsions/epilepsy.

- you have or have had any problems with drug or alcohol dependence.

- you are pregnant or intend to become pregnant.

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.

- 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.

If you have not told your doctor about any of the above, tell them before you are given TRAMADOL AN.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines 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 anti-depressants, mirtazapine, bupropion, tetrahydrocannabinol, phenothiazines or anti-psychotics
- some antibiotics.

These medicines may be affected by TRAMADOL AN, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Other interactions not listed above may also occur.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while you are being given TRAMADOL AN.

How TRAMADOL AN is given

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. Take them with you when you visit your doctor. Tramadol injections can be injected into a vein or a muscle.

If you are given too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (tel: 131 126) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have been given too much TRAMADOL AN. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are being given TRAMADOL AN injection.

Things you must 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. Do not take increased amounts or extra doses without checking with your doctor.

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 must 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.

Things to be careful of

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.

Side effects

Check with your doctor as soon as possible if you have any problems while you are being given TRAMADOL AN, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, TRAMADOL AN can cause side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

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

The most common side effects are:

- dizziness
- sedation, fatigue
- headache
- constipation
- nausea or vomiting
- sweating
- dry mouth

The following side effects are less common:

- indigestion
- hiccups
- changes in appetite
- skin reactions
- sudden onset of low blood pressure, collapse
- muscle weakness
- tremor
- seizures

- 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.

Tell your doctor immediately if you experience any of the following side-effects, as urgent medical treatment may be required:

- 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
- hallucinations
- convulsions.

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.

Other side effects not listed above may also occur in some patients.

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

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

After using TRAMADOL AN

Storage

Keep your TRAMADOL AN in the pack until it is time for it to be given to you.

If you take TRAMADOL AN out of the pack it may not keep well.

Keep it in a cool dry place where the temperature stays below 30° C. Do not store it in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least 1 1/2 metres above the ground is a good place to store medicines.

Disposal

If your TRAMADOL AN passes its expiry date or you no longer need it, ask your pharmacist what to do with any TRAMADOL AN that is left over.

TRAMADOL AN description

What it looks like

TRAMADOL AN is available as an injection solution containing tramadol hydrochloride 100mg/2mL.

It is a clear to slightly yellow coloured liquid contained in 2mL glass ampoules. Available in packs of 5 ampoules.

Ingredients

Active ingredient:

tramadol hydrochloride 100 mg in 2 mL ampoules

Inactive ingredients:

- sodium acetate
- water for injections.

TRAMADOL AN does not contain lactose, sucrose, tartrazine or any other azo dyes.

Sponsor

Juno Pharmaceuticals Pty Ltd
42 Kelso St
Cremorne VIC 3121

Date of Preparation:

June 2023

Registration Number:

TRAMADOL AN Injection
100mg/2mL:
AUST R 202840