

TRAMADOL AN INJECTION

Tramadol hydrochloride

Consumer Medicine Information

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 moderate to 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 not normally addictive although some cases have been reported.

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 are taking medicine for depression containing a "monoamine oxidase inhibitor" (such as Nardil, Parnate), or have taken one within the past two weeks.**

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.

Do not give TRAMADOL AN to children.

There is no experience with the use of TRAMADOL AN in children.

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:

1. you have a known allergy to tramadol or any of the ingredients listed at the end of this leaflet.
2. you are known to be sensitive to opioids.
3. you drink alcohol every day.
4. you have or ever had any other health problems, including:

- any lung or breathing problems
 - any diseases of the kidney, liver or pancreas
 - severe stomach problems
 - a serious head injury
 - any fits or convulsions/ epilepsy.
5. you have or have had any problems with drug or alcohol dependence.
 6. you are pregnant or intend to become pregnant. TRAMADOL AN is not recommended for use during pregnancy. Talk to your doctor about the risks and benefits of using TRAMADOL AN during pregnancy.
 7. 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 (SNRI's), 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
- how often

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.

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 taking 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 gets worse.

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.

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.

Things to be careful of

Be careful driving or operating machinery until you know how TRAMADOL AN affects you.

TRAMADOL AN may make you drowsy or dizzy.

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.

Tell your doctor if you notice any of the following and they worry you.

Common side effects:

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

Less common side effects:

- indigestion
- 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

Serotonin Syndrome: signs of this vary and are not specific: they may include fever, sweating, confusion, agitation, diarrhoea, muscle twitching, 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.

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.

Can TRAMADOL AN be addictive?

When given as prescribed by your doctor, addiction to TRAMADOL AN is unlikely.

If you are given TRAMADOL AN for a prolonged period of time, your body may become used to the medicine and mild withdrawal symptoms may occur if you suddenly stop taking the medicine. It is important therefore to use tramadol only as directed by your doctor, and do not suddenly stop taking it. Your dosage may need to be gradually reduced.

Tell your doctor if you are worried about addiction.

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
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TRAMADOL AN Injection 100mg/2mL:
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