

Tramadol Amneal Capsules

Tramadol hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Tramadol Amneal. 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 Amneal 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 Amneal is used for

Tramadol Amneal 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 Amneal for another reason. Ask your doctor why Tramadol Amneal has been prescribed for you.

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

Tramadol Amneal is not normally addictive although some cases have been reported.

Before you use Tramadol Amneal

When you must not use it

Do not use Tramadol Amneal if:

- **you have a known allergy to Tramadol Amneal 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.**

Do not use Tramadol Amneal after the expiry date printed on the pack.

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

Do not use Tramadol Amneal if the packaging is torn or shows signs of tampering.

Do not give Tramadol Amneal to children.

There is no experience with the use of Tramadol Amneal in children.

If you are not sure whether you should be using Tramadol Amneal, talk to your doctor.

Before you use it

You must tell your doctor if:

1. you have a known allergy to Tramadol Amneal 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 Amneal is not recommended for use during pregnancy. Talk to your doctor about the risks and benefits of using Tramadol Amneal during pregnancy.
 7. you are breast-feeding or plan to breast-feed.
Tramadol Amneal is not recommended for use during breast-feeding. Talk to your doctor about the risks and benefits of using Tramadol Amneal when breast-feeding.

If you have not told your doctor about any of the above, tell them before you use Tramadol Amneal.

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 Amneal. These include:

- carbamazepine (eg. Tegretol)
- coumarin derivatives (eg. Warfarin: Some Brand names are Coumadin, or Marevan)
- ondansetron
- medicine for irregular or rapid heart beat
- medicines for depression, sleeplessness or mental conditions such as selective serotonin reuptake inhibitors (SSRI's), tricyclic anti-depressants, quinidine, phenothiazines or anti-psychotics
- some antibiotics.

These medicines may be affected by Tramadol Amneal, 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 taking Tramadol Amneal.

How Tramadol Amneal is used

Tramadol Amneal is available as capsules (to swallow).

Your doctor will decide:

- what dose of Tramadol Amneal you will receive, and
- for how long.

How much to take

For moderate pain, one Tramadol Amneal capsule may be enough for the first dose, followed by one or two capsules two or three times a day as required.

For moderate to severe pain, two Tramadol Amneal capsules are usually required for the first dose, followed by one or two capsules every four to six hours as required. Patients over 75 years of age may require a lower daily dose.

Do not take more than eight Tramadol Amneal capsules per day.

Follow carefully all directions given to you by your doctor and pharmacist.

These directions may differ from the information in this leaflet. If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How to take it

Tramadol Amneal capsules should be swallowed whole, with water.

When to take it

You can take Tramadol Amneal before, with, or after food.

How long to take it

Depending on the medical condition for which you require Tramadol Amneal, your doctor may tell you to take it for only a day or two or longer, up to a few months or more.

If you forget to take it

If you forget to take a dose, you can take it as soon as you remember. The next dose should be taken after four or six hours, or as prescribed by your doctor.

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

If you take 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 taken too much Tramadol Amneal. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too many capsules, this may result in breathing difficulty and fits or convulsion.

While you are using Tramadol Amneal

Things you must do:

If you become pregnant while you are taking Tramadol Amneal, 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 Amneal.

If your pain is not severe and you feel that you do not need as much Tramadol Amneal as your doctor ordered, consult your doctor.

Tell your doctor if your pain gets worse. Do not take extra doses without checking with your doctor.

If you have to have any tests tell your doctor you are taking Tramadol Amneal. Tramadol Amneal may affect the results of some tests.

Things you must not do

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

Do not use Tramadol Amneal 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 Amneal affects you.

Tramadol Amneal may make you drowsy or dizzy.

Side effects

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

Like other medicines, Tramadol Amneal 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
- improvement 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 Amneal be addictive?

When used as prescribed by your doctor, addiction to Tramadol Amneal is unlikely.

If you are taking Tramadol Amneal 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 take Tramadol Amneal only as directed by your doctor, and do not suddenly stop taking it. Your dosage may need to be gradually reduced.

After using Tramadol Amneal

Storage

Keep your Tramadol Amneal in the pack until it is time to take them.

If you take Tramadol Amneal out of the pack it may not keep well.

Keep it in a cool dry place where the temperature stays below 25°C.

If ambient temperatures above 30°C and/or high humidity are likely to be experienced during ongoing storage, a cool, dry place should be sought to keep this medicine.

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 1½ metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Tramadol Amneal or it passes its expiry date, ask your pharmacist what to do with any Tramadol Amneal that is left over.

Tramadol Amneal description

What it looks like

Tramadol Amneal 50 mg capsules are hard gelatin capsules, size 3, having green cap and yellow body filled with a homogeneous white to off-white powder, containing tramadol hydrochloride 50 mg. They are available in a blister pack within a carton.

Ingredients

Active ingredient:

- Tramadol hydrochloride

Inactive ingredients:

- Microcrystalline cellulose
- Gelatin
- Indigo carmine aluminium lake
- Magnesium stearate
- Methyl hydroxybenzoate
- Propyl hydroxybenzoate
- Colloidal anhydrous silica
- Sodium lauryl sulphate
- Sodium starch glycollate
- Titanium dioxide

Distributor

Amneal Pharma Australia Pty Ltd
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