

CONSUMER MEDICINE INFORMATION

Arrow - Tramadol

Tramadol 50 mg capsules

WARNING

Limitations of use

ARROW- TRAMADOL 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

ARROW-TRAMADOL 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

ARROW-TRAMADOL 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 ARROW-TRAMADOL and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

Use of other medicines while using ARROW-TRAMADOL

Using ARROW-TRAMADOL 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 ARROW-TRAMADOL.

What is in this leaflet

This leaflet answers some common questions about ARROW - TRAMADOL.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking ARROW – TRAMADOL against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine. You may need to read it again.

What ARROW - TRAMADOL is used for

ARROW - TRAMADOL is used to relieve moderate to severe pain and belongs to a group of medicines called analgesics (pain relievers).

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

ARROW – TRAMADOL is available only with a doctor's prescription. 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 take ARROW - TRAMADOL

When you must not use it

Do not take ARROW – TRAMADOL if:

- **you have a known allergy to ARROW - TRAMADOL or any of the ingredients listed at the end of this leaflet.**
- **you have an allergy to any other medicines known as opioid analgesics, e.g. morphine or codeine**
- **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 MAOI (such as Nardil, Parnate), or have taken one within the past two weeks.**
- **you are an epileptic and your fits are uncontrolled or not adequately controlled by treatment.**
- **you have acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions)**
- **you are having treatment for withdrawal from narcotics**

Do not use ARROW - TRAMADOL 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 ARROW - TRAMADOL if the packaging is torn or shows signs of tampering.

Do not give ARROW - TRAMADOL Capsules to children under 12 years or to children between 12 – 18 years of age who are recovering from an operation to remove their tonsils and/or adenoids.

Addiction

You can become addicted to ARROW - TRAMADOL even if you take it exactly as prescribed. ARROW - TRAMADOL 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 taking ARROW - TRAMADOL. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking ARROW - TRAMADOL suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to ARROW - TRAMADOL 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 taking 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.

ARROW - TRAMADOL 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 using ARROW - TRAMADOL, talk to your doctor.

Before you use it

You must tell your doctor if:

1. you have a known allergy to ARROW - TRAMADOL or any of the ingredients listed at the end of this leaflet.
2. you are known to be sensitive to opioids.
3. you have, or have had, any drug or alcohol dependence.
4. you have or ever had any other health problems, including:
 - any lung or breathing problems
 - sleep-related breathing disorders
 - any diseases of the kidney, pancreas or liver
 - any stomach problems
 - severe headaches or feel sick due to a head injury
 - any fits or convulsions, or take medicines for epilepsy
5. you have had recent throat surgery or surgery to remove tonsils or adenoids.
6. you have or have had any problems with drug or alcohol dependence. If you know you are a CYP2D6 ultra-rapid metaboliser as this will affect how your body breaks down ARROW-TRAMADOL, and your dose of ARROW-TRAMADOL may need to be adjusted.
7. you are pregnant or intend to become pregnant. ARROW - TRAMADOL is not recommended for use during pregnancy. Talk to your doctor about the risks and benefits of using ARROW - TRAMADOL during pregnancy.
8. you are breast-feeding or plan to breast-feed. ARROW - TRAMADOL is not recommended for use during breast-feeding. Talk to your doctor about the risks and benefits of using ARROW - TRAMADOL when breast-feeding.

If you have not told your doctor about any of the above, tell them before you use ARROW - TRAMADOL.

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 ARROW - TRAMADOL. These include:

- carbamazepine
- coumarin derivatives used as blood thinning agents (eg. warfarin)
- a medicine for irregular or rapid heart beat
- medicines for depression, sleeplessness or mental conditions such as selective serotonin reuptake inhibitors (SSRI's), serotonin-noradrenaline reuptake inhibitors (SNRI's), tricyclic anti-depressants, phenothiazines or anti-psychotics
- 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 ARROW - TRAMADOL, 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 ARROW - TRAMADOL.

How to take ARROW - TRAMADOL

How much to take

Do not give ARROW - TRAMADOL Capsules to children under 12 years. There is no experience with the use of ARROW - TRAMADOL in children.

For adults, adolescents and children over the age of 12 years, the dosage depends on the severity of the pain.

For moderate pain, one ARROW - TRAMADOL 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 ARROW - TRAMADOL 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 or a longer time period between doses of ARROW- TRAMADOL compared to younger adults.

Do not take more than eight ARROW - TRAMADOL 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

ARROW - TRAMADOL capsules should be swallowed whole, with water.

When to take it

You can take ARROW - TRAMADOL before, with, or after food.

How long to take it

Depending on the medical condition for which you require ARROW - TRAMADOL, 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. This may increase the chance of you getting an unwanted side effect.

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

If you take too much (overdose)

Immediately telephone your doctor or the **Poisons Information Centre (phone 0800 POISON (0800 764 766))** or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much ARROW - TRAMADOL. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you or someone take too many capsules, they may experience one or more of the following symptoms:

- Slow, unusual or difficult breathing
- Drowsiness, dizziness or unconsciousness
- Slow or weak heartbeat
- Nausea or vomiting
- Convulsions or fits

When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

While you are taking ARROW - TRAMADOL

Things you must do

If you become pregnant while you are taking ARROW - TRAMADOL, tell your doctor immediately.

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

If your pain is not severe and you feel that you do not need as much ARROW – TRAMADOL 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 are about to have any blood tests, tell your doctor you are taking ARROW - TRAMADOL. ARROW - TRAMADOL may affect the results of some tests.

Tell any other doctors, dentists, and pharmacists who treat you, that you are taking this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

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.

Things you must not do

Do not give ARROW - TRAMADOL to anyone else, even if they have the same condition as you.

Do not use ARROW - TRAMADOL 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 ARROW - TRAMADOL affects you. ARROW - TRAMADOL may make you drowsy, dizzy, light-headed, tired 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 taking ARROW - TRAMADOL, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, ARROW - TRAMADOL 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.

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

The above list includes the more common side effects of your medicine.

The following list are less common side effects:

- indigestion
- hiccups
- changes in appetite
- skin reactions (eg. itching, rash)
- sudden onset of low blood pressure, collapse
- muscle weakness
- tremor
- seizures

- difficulty breathing
- improvement of mood
- confusion, anxiety
- sleep disturbance
- blurred vision
- difficulty in passing urine
- Serotonin Syndrome: signs of this vary and are not specific: they may include fever, sweating, agitation, tremor, muscle twitching, spontaneous muscle contraction. Serotonin Syndrome may result from interaction of tramadol with other medicines which increase serotonin effects, for example, the SSRI antidepressants.
- low blood sugar (hypoglycaemia)

This is not a complete listing. Occasionally, other side effects may be experienced.

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 taking ARROW - TRAMADOL:

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. If you have these symptoms, contact your doctor, who will decide if you need to take hormone supplement.

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.

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

After using ARROW - TRAMADOL

Storage

Keep ARROW - TRAMADOL 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.

Keep ARROW - TRAMADOL in a cool, dry place where the temperature stays below 25°C.

Keep your capsules in the packs until it is time to take them.

If you take the capsules out of the pack, they may not keep well.

**Do not store ARROW - TRAMADOL or other medicines in the bathroom or near a sink.
Do not leave the medicines in the car or on window sills.**

Heat, light and dampness can destroy some medicines.

Disposal

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

Product Description

What ARROW - TRAMADOL looks like

ARROW – TRAMADOL 50mg capsules are green/yellow coloured hard gelatin capsules filled with homogeneous white to off-white powder.

Ingredients

ARROW - TRAMADOL contains 50 mg tramadol hydrochloride as the active ingredient.

Each capsule also contains the following inactive ingredients: microcrystalline cellulose, sodium starch glycolate, colloidal anhydrous silica, magnesium stearate and purified water. The capsule shell contains yellow ferric oxide, indigo carmine, titanium dioxide, sodium lauryl sulfate, methyl parahydroxybenzoate, propyl parahydroxybenzoate and gelatin.

Supplier

ARROW - TRAMADOL is distributed in New Zealand by:

Teva Pharma (New Zealand) Limited
PO Box 128 244
Remuera
Auckland 1541
Telephone: 0800 800 097

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