

Module 1 - Administrative information and prescribing information**Product Name: TRAMADOL HYDROCHLORIDE AND ACETAMINOPHEN TABLETS USP**

1.3.3 Package Insert (also known as patient information PIL)**1. What TRAMADOL HYDROCHLORIDE AND ACETAMINOPHEN TABLETS USP is and what it is used for**

Tramadol Hydrochloride and Acetaminophen tablet is a combination of two analgesics Tramadol Hydrochloride and Acetaminophen. Tramadol is a narcotic-like pain killer. Acetaminophen is a less potent pain reliever that increases the effects of tramadol.

Acetaminophen And Tramadol Hydrochloride tablet is intended for use in the treatment of moderate to severe pain when your doctor recommends that a combination of tramadol and acetaminophen is needed.

2. Before You Take TRAMADOL HYDROCHLORIDE AND ACETAMINOPHEN TABLETS USP**Do not take Tramadol Hydrochloride and Acetaminophen Tablets USP if you:**

- Are allergic (hypersensitive) to Acetaminophen, Tramadol or any of the other ingredients of Tramadol hydrochloride/ Acetaminophen
- Have recently drunk a lot of alcohol
- Take any medicine that can make you sleepy or less alert; these include opioids containing pain relievers such as morphine and codeine
- Are currently taking monoamine oxidase inhibitors (MAOIs) for e.g. Depression or have taken any MAOIs within the last two weeks
- Suffer from severe liver problems
- Have epilepsy that is not adequately controlled on your current medicine.

Take special care with Tramadol Hydrochloride and Acetaminophen Tablets USP if you:

- Have kidney problems
- Have liver problems or alcoholic liver disease or you have noticed your eyes and skin turning yellow, which may suggest jaundice or problems with bile ducts
- Have difficulty breathing, for example, asthma or lung problems
- Are dependent on any other medicines used to relieve moderate to severe pain, for example, morphine
- Are epileptic or have you experienced fits or seizures
- Have suffered from a head injury, shock or severe headaches which may or may not be associated with vomiting.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Tramadol Hydrochloride and Acetaminophen Tablets USP should not be taken together with the following:

- Monoamine oxidase inhibitors (MAOIs)
- Opioids containing pain relievers such as morphine and codeine.

Tramadol Hydrochloride and Acetaminophen Tablets USP is not recommended to be taken with the following:

- Carbamazepine, commonly used to treat epilepsy or facial neuralgia (severe pain attacks in the face)
- Opioids, used to treat moderate to severe pain, e.g. buprenorphine, nalbuphine and pentazocine. In certain circumstances.

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Tramadol Hydrochloride and Acetaminophen Tablets USP may be taken with the following medicines:

- Serotonin reuptake inhibitors (SSRIs), used to treat depression. Serotonin Syndrome has been reported in a temporal connection with the therapeutic use of tramadol in combination with other serotonergic medicines such as selective serotonin re-uptake inhibitors and triptans.

Signs of Serotonin Syndrome may be for example, confusion, agitation, fever, sweating, uncoordinated movement of limbs or eyes (ataxia), uncontrollable jerking or twitching of muscles (hyperreflexia and myoclonus) and diarrhoea.

- Certain morphine-like medicines used, for example, to prevent or relieve coughing
- Sedatives, for example, benzodiazepines
- Sleeping pills, for example, barbiturates
- Certain medicines used to lower blood pressure
- Thalidomide
- Baclofen, used as a muscle relaxant
- Warfarin, used to thin the blood
- CYP3A4 inhibitors, for example, ketoconazole (an antifungal) or erythromycin (an antibacterial)
- Bupropion, used to help people to stop smoking
- Tricyclic antidepressants
- Tranquillisers.

Taking the following medicines together with Tramadol Hydrochloride and Acetaminophen Tablets USP may affect how Tramadol Hydrochloride and Acetaminophen Tablets USP works in your body:

- Metoclopramide and domperidone, used in nausea and vomiting
- Cholestyramine, used to treat diarrhoea and itchy skin.

Surgery and tests:

Tell your doctor or dentist that you are taking Tramadol Hydrochloride and Acetaminophen tablets before you have a general anaesthetic.

Taking Tramadol Hydrochloride and Acetaminophen Tablets USP with food and drink:

Tramadol Hydrochloride and Acetaminophen Tablets can be taken with or without food.

Tramadol Hydrochloride and Acetaminophen Tablets may make you feel drowsy. Alcohol may make you feel drowsier. Alcohol: increases the sedative effect of opioid analgesics, the effect on alertness can make driving of vehicles and the use of machines dangerous, avoid intake of alcoholic drinks and of medicinal products containing alcohol.

Pregnancy and breast-feeding:

Ask your doctor or pharmacist for advice before taking any medicine.

Since Tramadol Hydrochloride and Acetaminophen Tablet is a fixed combination of active ingredients including tramadol, it should not be used during pregnancy and breast-feeding.

Driving and using machines

Do not drive, operate machinery or perform other activities for which you need to be alert until you know how Tramadol Hydrochloride and Acetaminophen Tablet affects you. Tramadol Hydrochloride and Acetaminophen Tablet may make you feel drowsy.

3. How To Take TRAMADOL HYDROCHLORIDE AND ACETAMINOPHEN TABLETS USP

Always take Tramadol Hydrochloride and Acetaminophen Tablet exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual starting dose is two tablets. If required, further doses can be taken after every six hours, as recommended by your doctor.

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Do not take more than 8 tablets per day (equivalent to 300 mg tramadol and 2600 mg acetaminophen). If you are over 75 years old or have a history of kidney or liver problems, your doctor may increase the time between doses.

Tramadol Hydrochloride and Acetaminophen Tablet is not recommended for use in children under 12 years.

It is recommended that the minimum interval between doses should be not less than 6 hours, due to the presence of tramadol.

The tablets must be swallowed whole with some liquid. They should not be broken or chewed.

The tablets should be taken for as short a time as possible.

If you think that the effect of Tramadol Hydrochloride and Acetaminophen Tablet is too strong (i.e. you feel very drowsy or have difficulty with breathing) or too weak (i.e. you have inadequate pain relief), contact your doctor or pharmacist. If your symptoms do not get any better, see your doctor.

If you take more Tramadol Hydrochloride and Acetaminophen Tablet than you should

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

If you forget to take Tramadol Hydrochloride and Acetaminophen Tablet

Do not take a double dose to make up for a forgotten tablet.

If you miss a dose of Acetaminophen And Tramadol Hydrochloride Tablets, take your next tablet at the usual time.

If you stop taking Tramadol Hydrochloride and Acetaminophen Tablet

If you have been using Tramadol Hydrochloride and Acetaminophen Tablet for some time, you should talk to your doctor if you want to stop because your body may have got used to it. If you do suddenly stop using Tramadol Hydrochloride and Acetaminophen Tablet you may feel unwell. You may experience anxiety, agitation, nervousness, sleeplessness, hyperactivity, tremors and/or an upset stomach.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible Side Effects of TRAMADOL HYDROCHLORIDE AND ACETAMINOPHEN TABLETS USP

Like all medicines, Tramadol Hydrochloride and Acetaminophen Tablet can cause side effects, although not everybody gets them.

If you do notice any of these effects, or any other unusual symptoms, please tell your doctor or pharmacist as soon as possible.

The very common (occurring in more than one out of 10 treated individuals) side effects may include:

- Nausea
- Dizziness
- Drowsiness.

These are usually mild and not troublesome.

Common (occurring in less than one out of 10, but in more than one out of 100 treated individuals) side effects may include:

- Vomiting
- Constipation
- Flatulence
- Diarrhoea
- Stomach pain

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Uncommon (occurring in less than one out of 100, but in more than one out of 1,000 treated individuals) **side effects include:**

- High blood pressure, heart rhythm and heart rate disorders
- Difficulty or pain on passing urine/protein in the urine
- Skin reactions/hives
- Ringing in the ear
- Depression
- Nightmares

Rare (occurring in less than one out of 1,000, but in more than one out of 10,000 treated individuals) **side effects include:**

- Uncoordinated movements
- Fits (convulsions)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How To Store TRAMADOL HYDROCHLORIDE AND ACETAMINOPHEN TABLET USP

- Keep tramadol hydrochloride and acetaminophen tablet out of the sight and reach of children.
- Store in a dry place at a temperature below 30°C.
- Do not take the tablets after the expiry date which is stated on the carton. The expiry date is also stated on the back of the strip after 'Exp'.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information**What TRAMADOL HYDROCHLORIDE AND ACETAMINOPHEN TABLET USP contains:**

- The active substances (the ingredients that make the tablet work) are Tramadol Hydrochloride and Acetaminophen.
- The other ingredients are Maize Starch, Colloidal Silicon Dioxide, Microcrystalline Cellulose, Sodium Benzoate, Demineral Water, Povidone, Magnesium Stearate, Purified Talc, Sodium Starch Glycolate, Iron Oxide Yellow colour, Acetone, Isopropyl Alcohol, Wesco Coating Material.

What TRAMADOL HYDROCHLORIDE AND ACETAMINOPHEN TABLET USP looks like
Yellow colour round shape biconvex film coated tablet.