

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

Pr **TRAMADOL-ACET**
Tramadol Hydrochloride/Acetaminophen Tablets
USP

This leaflet is part III of a three-part “Product Monograph” published when TRAMADOL-ACET was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about TRAMADOL-ACET. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

TRAMADOL-ACET (tramadol hydrochloride/acetaminophen) is an analgesic. An analgesic is a medication that is used to relieve pain. TRAMADOL-ACET tablets are prescribed by doctors for the management of moderate pain, or moderately severe pain. Your doctor is the person who knows if TRAMADOL-ACET tablets are a good choice for you.

What it does:

TRAMADOL-ACET tablets have a combination of two pain relievers - tramadol hydrochloride (an opioid analgesic) and acetaminophen. You may already be familiar with acetaminophen (one brand sold as TYLENOL*) which acts quickly to relieve pain. Tramadol hydrochloride is a pain reliever that works over several hours to maintain pain relief. Because these two ingredients work together, TRAMADOL-ACET tablets relieve your pain quickly and help that pain relief last longer.

When it should not be used:

You should not use TRAMADOL-ACET if you are allergic to tramadol, acetaminophen, opioids or to any of the nonmedicinal ingredients in the product (see **What the nonmedicinal ingredients are**). Contact your doctor immediately if you experience an allergic reaction such as wheezing, skin rash, itching or hives or any severe or unusual side effects.

You should never take TYLENOL or any other products containing acetaminophen with TRAMADOL-ACET.

TRAMADOL-ACET should not be used for minor pain that can be relieved by readily available (over-the-counter) painkillers.

Children under 18 years of age should not take TRAMADOL-ACET tablets.

Use of TRAMADOL-ACET tablets in pregnant women is not recommended. It is not clear what effects the medication would have on the fetus.

TRAMADOL-ACET tablets are not recommended for obstetrical preoperative medication or for post-delivery

analgesia in nursing mothers because its safety in infants and newborns has not been studied.

If you have had seizures (convulsions) or have a condition that may put you at increased risk of seizures (epilepsy, head injury, metabolic disorders, alcohol or drug withdrawal), if you are taking monoamine oxidase (MAO) inhibitors, have an infection of the central nervous system, or are taking antidepressant medication, do not take this medication before discussing your history with your doctor.

Like some pain relievers, TRAMADOL-ACET tablets may be habit-forming. TRAMADOL-ACET tablets may not be the best medicine for you if you have had problems with addiction, drug dependence, or drug abuse in the past. Tell your doctor and pharmacist if you have had these conditions before.

What the medicinal ingredients are:

TRAMADOL-ACET tablets combine two centrally acting analgesic, tramadol and acetaminophen.

What the important nonmedicinal ingredients are:

Nonmedicinal ingredients for TRAMADOL-ACET are: microcrystalline cellulose, croscarmellose sodium, pregelatinized starch, povidone, stearic acid, hydroxypropyl methylcellulose, hydroxypropyl cellulose, polyethylene glycol, titanium dioxide and yellow ferric oxide.

What dosage forms it comes in:

Each TRAMADOL-ACET tablet contains 37.5 mg tramadol hydrochloride, and 325 mg acetaminophen.

WARNINGS AND PRECAUTIONS

Before starting TRAMADOL-ACET and to get the best possible treatment, be sure to tell your doctor if you

- suffer from serious liver or kidney disease,
- have abdominal problems,
- have had a previous head injury,
- have chronic alcoholism,
- are pregnant or plan to become pregnant,
- are breast-feeding, and
- if you are taking any other medications including natural health products, prescription drugs, salicylates, other pain and fever relief medications or nonsteroidal anti-inflammatory drugs (NSAIDs).

This will help your doctor to decide whether you should use TRAMADOL-ACET and what extra care should be taken during its use.

If you are planning surgery, or about to undergo surgery, tell your doctor that you are taking TRAMADOL-ACET.

IMPORTANT: PLEASE READ

You should take the following precautions while taking TRAMADOL-ACET tablets:

Alcohol

You should not take TRAMADOL-ACET tablets with any alcohol containing beverages. Also, you should tell your doctor if you drink alcohol regularly, or have a history of alcoholism.

Driving or operating machinery

Do not drive a car or operate other potentially hazardous machinery until you are sure that taking TRAMADOL-ACET does not make you drowsy.

Other medications

You should not take other medications that contain acetaminophen (including over-the-counter preparations containing acetaminophen) or tramadol while you are taking TRAMADOL-ACET tablets.

There are also other drugs, such as tranquilizers, antidepressants, hypnotics, sleeping pills, certain Parkinson's disease medications, or other analgesics, that can cause some serious reactions when taken by someone who is also taking TRAMADOL-ACET tablets. You must tell your doctor and pharmacist if you are taking any other medications—they will tell you what you should do.

INTERACTIONS WITH THIS MEDICATION

There are other medications that may cause TRAMADOL-ACET tablets to be less effective, or may cause you to have some side effects or drug reactions.

Drugs that may interact with TRAMADOL-ACET include: fluoxetine, paroxetine, quinidine, amitriptyline, carbamazepine, MAO inhibitors and serotonin reuptake inhibitors, digoxin, warfarin-like compounds.

You must tell your doctor and pharmacist if you are taking any other medications.

PROPER USE OF THIS MEDICATION

Usual adult dose:

You may take your TRAMADOL-ACET tablets with or without food. Take the tablets only as directed by your doctor. It is very important that you do not take more tablets than your doctor advised. Usually, 1 or 2 tablets are taken every 4 to 6 hours when needed for relief of pain. When you first begin taking your tablets, your doctor may ask you to start slowly and gradually increase the number of tablets you take.

However, you should not take more than 8 tablets per day. Exceeding these recommendations can result in respiratory depression (shallow, slow breathing), seizures, liver damage, coma, heart stoppage and death. Taking a significant overdose can result in hepatic toxicity.

In patients with kidney problems, the time between doses may

be longer. Please speak with your doctor.

Discontinuation:

Stopping the TRAMADOL-ACET tablets too quickly may cause some side effects, so your doctor may ask you to gradually stop taking your medication over several days. To get the full benefit from your treatment, it is important to take TRAMADOL-ACET tablets as prescribed.

Overdose:

In case of accidental Overdose: Call a Poison Control Centre or doctor immediately, even if you do not notice any signs or symptoms such as increased sweating, nausea, vomiting, stomach pain or loss of appetite.

Signs and symptoms of liver damage may develop 1 to 2 days after taking an overdose.

Missed Dose:

If you miss a dose, take it as soon as you remember. But, if it is almost time for the next dose, do not take the missed dose. Instead, take the next scheduled dose. Do not try to make up for the missed dose by taking a double dose next time.

SIDE EFFECTS AND WHAT TO DO ABOUT

Most medications have some side effects; however, not all people have the same side effects, and some people experience few, if any, side effects. When taking TRAMADOL-ACET tablets the most common side effects include nausea, vomiting, constipation, headache, dizziness and sleepiness. If you experience serious symptoms or any other unusual symptoms, tell your doctor immediately.

If you experience serious symptoms from allergic reaction such as wheezing, skin rash, itching or hives, difficulty in breathing, lethargy, pallor (paleness), tell your doctor immediately.

Physical dependence, abuse and withdrawal reactions have been rarely reported. See withdrawal reactions listed within the 'Discontinuation' section of this leaflet.

This is not a complete list of side effects. For any unexpected effects while taking TRAMADOL-ACET, contact your doctor or pharmacist.

HOW TO STORE IT

TRAMADOL-ACET tablets should be stored at room temperature 15- 30°C (59-86°F).

IMPORTANT: PLEASE READ

Do not use TRAMADOL-ACET tablets after the expiry date. All expired medications should be returned to your pharmacist.

Keep this and all medicines in a safe place away from children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701 E
Ottawa, ON KIA OK9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, please contact your doctor, pharmacist or other healthcare professional.

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

This leaflet was prepared by
Pro Doc Ltée, Laval, Québec, H7L 3W9

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