

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION**

**PrTRAMACET®
tramadol hydrochloride and acetaminophen tablets, USP**

Read this carefully before you start taking TRAMACET® and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about TRAMACET®.

Serious Warnings and Precautions

- **Even if you take TRAMACET® as prescribed you are at a risk for opioid addiction, abuse and misuse. This can lead to overdose and death.**
- **When you take TRAMACET® it must be swallowed whole. Do not cut, break, crush, chew or dissolve the tablet. This can be dangerous and can lead to death or seriously harm you.**
- **You may get life-threatening breathing problems while taking TRAMACET®. This is less likely to happen if you take it as prescribed by your doctor. Babies are at risk of life-threatening breathing problems if their mothers take opioids while pregnant or nursing.**
- **You should never give anyone your TRAMACET®. They could die from taking it. If a person has not been prescribed TRAMACET®, taking even one dose can cause a fatal overdose. This is especially true for children.**
- **If you took TRAMACET® while you were pregnant, whether for short or long periods of time or in small or large doses, your baby can suffer life-threatening withdrawal symptoms after birth. This can occur in the days after birth and for up to 4 weeks after delivery. If your baby has any of the following symptoms:**
 - **has changes in their breathing (such as weak, difficult or fast breathing)**
 - **is unusually difficult to comfort**
 - **has tremors (shakiness)**
 - **has increased stools, sneezing, yawning, vomiting, or fever****Seek immediate medical help for your baby.**
- **Liver injury: Liver injury can occur when more than the maximum daily dose of acetaminophen is taken. Follow your doctor's instructions to know how much acetaminophen you can take in a day. Acetaminophen can be in oral solutions/drops, syrup, pills, capsules, suppositories, intravenous solutions, etc. To calculate how much acetaminophen you have had in a day, read the labels on all products to see if they contain acetaminophen. Keep track of how much acetaminophen is in each dose and how much you have taken in a 24-hour period. Seek medical attention as soon as an acetaminophen overdose is suspected. Do not wait for symptoms to appear (see Overdose).**
- **Taking TRAMACET® with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.**

What is TRAMACET® used for?

TRAMACET® (tramadol hydrochloride and acetaminophen) is used to manage your pain.

How does TRAMACET® work?

TRAMACET® is a painkiller belonging to the class of drugs known as opioids. It relieves pain by acting on specific nerve cells of the spinal cord and brain.

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

What are the ingredients in TRAMACET®?

Medicinal ingredients: tramadol and acetaminophen.

Nonmedicinal ingredients: carnauba wax, hypromellose, polyethylene glycol, polysorbate 80, powdered cellulose, pregelatinized starch, magnesium stearate, sodium starch glycolate, starch, titanium dioxide, and yellow iron oxide.

TRAMACET® comes in the following dosage forms:

Each TRAMACET® tablet contains 37.5 mg tramadol hydrochloride, and 325 mg acetaminophen.

Do not use TRAMACET® if:

- you are allergic to tramadol, acetaminophen, opioids or to any of the other ingredients in TRAMACET® (see **What are the ingredients in TRAMACET®?**)
- you can control your pain by the occasional use of other pain medications. This includes those available without a prescription
- you have severe asthma, trouble breathing, or other breathing problems
- you have bowel blockage or narrowing of the stomach or intestines or have been told that you are at risk for this
- you have severe pain in your abdomen
- you have a head injury
- you suffer from severe reduction in functions controlled by the brain such as breathing, heart rate and consciousness, or if you have increased pressure in your head or spinal cord
- you are at risk for seizures
- you have severe kidney disease
- you have severe liver disease
- you suffer from alcoholism, severe alcohol withdrawal or have a seizure disorder
- you are taking, or have taken within the past 2 weeks, a monoamine oxidase (MAO) inhibitor medication (e.g., phenelzine sulfate, tranylcypromine sulfate, moclobemide or selegiline)
- you are pregnant, plan to become pregnant, in labour or nursing
- you are less than 18 years old and are having (or have recently had) your tonsils or adenoids removed because of frequent interruption of breathing during sleep
- you are less than 12 years old
- you have slow or shallow breathing, elevated carbon dioxide levels in the blood or a condition called “cor pulmonale” in which part of the heart is enlarged or does not work correctly due to high blood pressure in the lungs

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TRAMACET®. Talk about any health conditions or problems you may have, including if you:

- have a history of illicit or prescription drug or alcohol abuse
- have low blood pressure
- have or had depression
- suffer from chronic or severe constipation
- have been told that you metabolize tramadol or other pain medications rapidly
- have problems with your thyroid, adrenal or prostate gland
- have, or had in the past hallucinations or other severe mental problems
- have liver or kidney problems
- have diabetes
- are over 65 years of age
- have abdominal problems
- suffer from migraines
- are at risk of low sodium levels in your blood

Other warnings you should know about:

TRAMACET® can decrease your blood sugar levels. Diabetic patients may need to monitor their blood sugar more often. If you notice changes, discuss this with your doctor.

If you are planning surgery, or about to undergo surgery, tell your doctor that you are taking TRAMACET®.

Opioid dependence and addiction: There are important differences between physical dependence and addiction. It is important that you talk to your doctor if you have questions or concerns about abuse, addiction or physical dependence.

Pregnancy, nursing, labour and delivery:

Do not use TRAMACET® while pregnant, nursing, during labour or delivery. Opioids can be transferred to your baby through breast milk, or while still in the womb. TRAMACET® can then cause life-threatening breathing problems in your unborn baby or nursing infant.

Adolescents (12 to 18 years old): You should not use TRAMACET® if your child:

- is overweight (obese)
- has obstructive sleep apnea (a condition where your breathing starts and stops while you sleep)
- has severe lung disease

There is a higher risk of serious breathing problems if your child takes TRAMACET and has any of the above conditions.

Driving and using machines: Before you do tasks which may require special attention, you should wait until you know how you react to TRAMACET®. TRAMACET® can cause:

- drowsiness
- dizziness or
- lightheadedness

This can usually occur after you take your first dose and when your dose is increased.

Disorder of the adrenal gland: You may develop a disorder of the adrenal gland called adrenal insufficiency. This means that your adrenal gland is not making enough of certain hormones. You may experience symptoms such as:

- nausea, vomiting
- feeling tired, weak or dizzy
- decreased appetite

You may be more likely to have problems with your adrenal gland if you have been taking opioids for longer than one month. Your doctor may do tests, give you another medication, and slowly take you off TRAMACET®.

Serotonin Syndrome: TRAMACET® can cause Serotonin Syndrome, a rare but potentially life-threatening condition. It can cause serious changes in how your brain, muscles and digestive system work. You may develop Serotonin Syndrome if you take TRAMACET® with certain anti-depressants or migraine medications.

Serotonin Syndrome symptoms include:

- fever, sweating, shivering, diarrhea, nausea, vomiting;
- muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination;
- fast heartbeat, changes in blood pressure;
- confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma.

Sexual Function/Reproduction: Long term use of opioids may lead to a decrease in sex hormone levels. It may also lead to low libido (desire to have sex), erectile dysfunction or being infertile.

You should take the following precautions while taking TRAMACET® tablets:

In some individuals tramadol acts more rapidly than in others. This may cause an overdose even at the recommended dose. Seek immediate medical attention if you experience slow breathing or overdose symptoms such as extreme sleepiness, confusion, or shallow breathing.

Serious skin reactions (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis, Hypersensitivity Syndrome)
Acetaminophen can cause serious skin reactions that can spread to your mouth, lips, face, hands, trunk, arms and legs. This condition is life-threatening.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with TRAMACET®:

- Alcohol. This includes prescription and non-prescription medications that contain alcohol. Do not drink alcohol while you are taking TRAMACET®. It can lead to:
 - drowsiness
 - unusually slow or weak breathing
 - serious side effects or
 - a fatal overdose
- other opioid analgesics (drugs used to treat pain)
- general anesthetics (drugs used during surgery)

- benzodiazepines (drugs used to help you sleep or that help reduce anxiety)
- antidepressants (for depression and mood disorders) such as selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs) (e.g., venlafaxine and duloxetine), certain tricyclic antidepressants (e.g., imipramine and amitriptyline) or other tricyclic compounds (e.g., cyclobenzaprine, promethazine) or lithium and St. John's Wort. **Do not** take TRAMACET[®] with MAO inhibitors (MAOi) or if you have taken MAOi's in the last 14 days.
- drugs used to treat serious mental or emotional disorders (such as schizophrenia)
- antihistamines (drugs used to treat allergies)
- anti-emetics (drugs used for the prevention of vomiting)
- drugs used to treat muscle spasms and back pain
- warfarin (such as coumadin) and other anticoagulants (used for prevention or treatment of blood clots)
- anti-retroviral drugs (used to treat viral infections)
- anti-fungal drugs (used to treat fungal infections)
- antibiotic drugs (used to treat bacterial infections)
- some heart medication (such as beta-blockers)
- drugs used to treat migraines (e.g., triptans)
- drugs containing tryptophan
- carbamazepine, used to treat epilepsy and some types of pain
- quinidine, used to treat heart conditions (antiarrhythmics)
- grapefruit juice

Medicines that may increase the risk of hyponatremia (low sodium in the blood) such as antidepressants, benzodiazepines, diuretics.

How to take TRAMACET[®]:

Swallow whole. Do not cut, break, crush, chew or dissolve the tablet. This can be dangerous and can lead to death or seriously harm you.

Do not take other medications that contain acetaminophen (including over-the-counter preparations containing acetaminophen) or tramadol while you are taking TRAMACET[®] tablets.

You may take your TRAMACET[®] tablets with or without food.

Usual Adult Starting Dose:

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.

Your dose is tailored/personalized just for you. Be sure to follow your doctor's dosing instructions exactly. Do not increase or decrease your dose without consulting your doctor.

Review your pain regularly with your doctor to determine if you still need TRAMACET[®]. Be sure to use TRAMACET[®] only for the condition for which it was prescribed.

If your pain increases or you develop any side effect as a result of taking TRAMACET[®], tell your doctor immediately.

Stopping your Medication

If you have been taking TRAMACET[®] for more than a few days you should not stop taking it all of a sudden. You should check with your doctor for directions on how to slowly stop taking it. You should do it slowly to avoid uncomfortable symptoms such as having:

- body aches
- diarrhea
- gooseflesh
- loss of appetite
- nausea
- feeling nervous or restless
- runny nose
- sneezing
- tremors or shivering
- stomach cramps
- rapid heart rate (tachycardia)
- having trouble sleeping
- an unusual increase in sweating
- an unexplained fever
- weakness
- yawning

By reducing or stopping your opioid treatment, your body will become less used to opioids. If you start treatment again, you will need to start at the lowest dose. You may overdose if you restart at the last dose you took before you slowly stopped taking TRAMACET[®].

Refilling your Prescription for TRAMACET[®]:

A new written prescription is required from your doctor each time you need more TRAMACET[®]. Therefore, it is important that you contact your doctor before your current supply runs out.

Only obtain prescriptions for this medicine from the doctor in charge of your treatment. Do not seek prescriptions from other doctors unless you switch to another doctor for your pain management.

Overdose:

If you think you have taken too much TRAMACET[®], contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Signs of overdose may include:

- unusually slow or weak breathing
- dizziness

- confusion
- extreme drowsiness
- fits (seizures)
- irritation and discomfort in the stomach and gut
- loss of appetite
- nausea
- vomiting,
- feeling unwell
- unusually pale color and sweating

Signs and symptoms of liver damage may develop 1 to 2 days after taking an overdose of acetaminophen, such as increased sweating, nausea, vomiting, stomach pain or loss of appetite, yellowing of the skin/eyes, dark urine.

Cases of abnormal electrical conduction in the heart (QT prolongation) have been reported.

Missed Dose:

If you miss one dose, take it as soon as possible. However, if it is almost time for your next dose, then skip the missed dose. Do not take two doses at once. If you miss several doses in succession, talk to your doctor before restarting your medication.

What are possible side effects from using TRAMACET®?

These are not all the possible side effects you may feel when taking TRAMACET®. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Drowsiness
- Insomnia
- Dizziness
- Fainting
- Nausea, vomiting, or a poor appetite
- Dry mouth
- Headache
- Problems with vision
- Weakness, uncoordinated muscle movement
- Itching
- Sweating
- Constipation
- Low sex drive, impotence (erectile dysfunction), infertility

Talk with your doctor or pharmacist about ways to prevent constipation when you start using TRAMACET®.

TRAMACET® can cause abnormal blood test results including decreased blood sugar. Your doctor will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
Overdose: hallucinations, confusion, inability to walk normally, slow or weak breathing, extreme sleepiness, sedation, or dizziness, floppy muscles/low muscle tone cold and clammy skin			✓
Respiratory Depression: slow, shallow or weak breathing			✓
Allergic Reaction: rash, hives, swelling of the face, eyes, lips, tongue or throat, difficulty swallowing or breathing			✓
Bowel Blockage (impaction): abdominal pain, severe constipation, nausea			✓
Withdrawal: nausea, vomiting, diarrhea, anxiety, shivering, cold and clammy skin, body aches, loss of appetite, sweating		✓	
Fast, Slow or Irregular Heartbeat: heart palpitations		✓	
Low Blood Pressure: dizziness, fainting, light-headedness	✓		
Serotonin Syndrome: agitation or restlessness, loss of muscle control or muscle twitching, tremor, diarrhea			✓
VERY RARE			
Hyponatremia (low sodium in the blood): lethargy, confusion, muscular twitching, seizure and coma			✓
Decreased Blood Sugar (hypoglycemia): dizziness, lack of energy, drowsiness, headache, trembling, sweating			✓
Serious Skin Reactions (Stevens - Johnson Syndrome, Toxic Epidermal Necrolysis, Hypersensitivity Syndrome): any combination of itchy skin			✓

rash, redness, blistering and peeling of the skin and/or of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or joint pain, yellowing of the skin or eyes, dark urine			
Liver Injury: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect®: <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 1908C
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect® (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

TRAMACET® tablets should be stored at room temperature (15°C to 30°C).

Do not use TRAMACET® tablets after the expiry date. All expired medications should be returned to your pharmacist.

Keep unused or expired TRAMACET® in a secure place to prevent theft, misuse or accidental exposure.

Keep TRAMACET® out of sight and reach of children and pets.

Disposal:

TRAMACET® should never be thrown into household trash, where children and pets may find it. It should be returned to a pharmacy for proper disposal.

If you want more information about TRAMACET®:

- Talk to your healthcare professional
- For questions or concerns, please contact the manufacturer, Janssen Inc. (www.janssen.com/canada)
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.janssen.com/canada), or by calling 1-800-567-3331 or 1-800-387-8781.

This leaflet was prepared by
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