

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

**PrULTRAM®
tramadol hydrochloride Tablets, USP**

Read this carefully before you start taking **ULTRAM®** 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 **ULTRAM®**.

Serious Warnings and Precautions

- **Even if you take ULTRAM® as prescribed you are at a risk for opioid addiction, abuse and misuse. This can lead to overdose and death.**
- **Do not 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 ULTRAM®. 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 ULTRAM®. They could die from taking it. If a person has not been prescribed ULTRAM®, taking even one dose can cause a fatal overdose. This is especially true for children.**
- **If you took ULTRAM® 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.**
- **Taking ULTRAM® 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 ULTRAM® used for?

ULTRAM® is used to manage your pain.

How does ULTRAM® work?

ULTRAM® 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.

What are the ingredients in ULTRAM®?

Medicinal ingredient: tramadol

Non-medicinal ingredients: carnauba wax, corn starch, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, sodium starch glycolate and titanium dioxide

ULTRAM® comes in the following dosage forms:

50 mg tablets

Do not use ULTRAM® if:

- you are allergic to tramadol or any of the other ingredients in ULTRAM® (see **What are the ingredients in ULTRAM®?**)
- 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
- 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
- you are taking or have taken within the past 2 weeks a Monoamine Oxidase inhibitor (MAOi) (such as phenelzine sulfate, tranylcypromine sulfate, moclobemide or selegiline)
- 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 ULTRAM®. 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
- are at risk of low sodium levels in your blood
- have liver or kidney problems
- have diabetes
- are over 65 years of age
- have abdominal problems
- suffer from migraines
- are pregnant or plan to become pregnant
- are nursing

Other warnings you should know about:

ULTRAM[®] 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 ULTRAM[®].

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: Opioids can be transferred to your baby through breast milk, or while still in the womb. ULTRAM[®] can then cause life-threatening breathing problems in your unborn baby or nursing infant. Your doctor will determine if the benefits of using ULTRAM[®] outweigh the risks to your unborn baby or nursing infant.

If you are pregnant and are taking ULTRAM[®], it is important that you don't stop taking your medication all of a sudden. Your doctor will monitor and guide you on how to slowly stop taking ULTRAM[®]. This may help avoid serious harm to your unborn baby.

Adolescents (12 to 18 years old): You should not use ULTRAM[®] 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 ULTRAM[®] 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 ULTRAM[®]. ULTRAM[®] can cause:

- drowsiness
- dizziness or
- light-headedness

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 ULTRAM[®].

Serotonin Syndrome: ULTRAM[®] 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 ULTRAM[®] 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.

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 ULTRAM®:

- Alcohol. This includes prescription and non-prescription medications that contain alcohol. **Do not** drink alcohol while you are taking ULTRAM®. 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 ULTRAM® 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 ULTRAM®:

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

Do not take ULTRAM® tablets with other tramadol-containing products.

You may take ULTRAM® tablets with or without food.

Usual Adult Starting Dose:

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 ULTRAM®. Be sure to use ULTRAM® only for the condition for which it was prescribed.

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

When you first begin taking ULTRAM®, 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.

Stopping your Medication

If you have been taking ULTRAM® 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 ULTRAM®.

Refilling your Prescription for ULTRAM®:

A new written prescription is required from your doctor each time you need more ULTRAM®. 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 ULTRAM®, 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 colour and sweating

Cases of abnormal electrical conduction of 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 ULTRAM®?

These are not all the possible side effects you may feel when taking ULTRAM®. 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 ULTRAM®.

ULTRAM® 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, 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 | | | ✓ |

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

We encourage you to report serious or unexpected side effects to Health Canada. The information is used to check for new safety concerns about health products. As a consumer, your report contributes to the safe use of health products for everyone.

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

Storage:

ULTRAM® tablets should be stored at room temperature (15°C to 30°C). **Keep unused or expired ULTRAM® in a secure place to prevent theft, misuse or accidental exposure.**

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

Disposal:

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

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

If you want more information about ULTRAM®:

- 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:
Janssen Inc.
Toronto, Ontario, M3C 1L9

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