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Ultracet

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Description

Side Effects Nausea, vomiting, constipation, lightheadedness, dizziness, drowsiness, or sweating may occur. Some of these side effects may decrease after you have been using this medication for a while. If any of these effects last or get worse, tell your doctor or pharmacist promptly. To prevent constipation, eat dietary fiber, drink enough water, and exercise. You may also need to take a laxative. Ask your pharmacist which type of laxative is right for you. To reduce the risk of dizziness and lightheadedness, get up slowly when rising from a sitting or lying position. Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor right away if you have any serious side effects, including: interrupted breathing during sleep (sleep apnea), mental/mood changes (such as agitation, hallucinations), severe stomach/abdominal pain, difficulty urinating, signs of your adrenal glands not working well (such as loss of appetite, unusual tiredness, weight loss). Get medical help right away if you have any very serious side effects, including: fast/irregular heartbeat, severe dizziness, fainting, seizure. This medication may increase serotonin and rarely cause a very serious condition called serotonin syndrome/toxicity. The risk increases if you are also taking other drugs that increase serotonin, so tell your doctor or pharmacist of all the drugs you take (see Drug Interactions section). Get medical help right away if you develop some of the following symptoms: fast heartbeat, hallucinations, loss of coordination, severe dizziness, severe nausea/vomiting/diarrhea, twitching muscles, unexplained fever, unusual agitation/restlessness. Tramadol is changed into a strong opioid drug in your body. In some people, this change happens faster and more completely than usual, which increases the risk of very serious side effects. Get medical help right away if you notice any of the following: slow/shallow breathing, severe drowsiness/difficulty waking up, confusion. A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any of the following symptoms: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US – Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch. In Canada – Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345. How long does it take for this medicine to take effect? The onset of action for Ultracet can typically be expected within an hour of oral ingestion. Tramadol, one of its active ingredients, reaches its peak plasma concentration approximately two hours after oral administration, contributing to the analgesic

effect. How long do the effects of this medicine last? The effects of Ultracet generally last for about 4 to 6 hours. This duration can vary depending on individual factors such as metabolism, the severity of pain, and dosage. Is it safe to consume alcohol while taking this medicine? It is not safe to consume alcohol while taking Ultracet. Alcohol can increase the sedative effects of tramadol, potentially leading to dangerous side effects such as respiratory depression, profound sedation, or coma. Additionally, alcohol and acetaminophen together increase the risk of acute liver failure, a potentially life-threatening condition. Is this a habit forming medicine? Ultracet has a potential for habit formation, primarily due to the presence of tramadol. Tramadol can lead to physical or psychological dependence, especially with prolonged use or misuse. It is important to use Ultracet strictly as prescribed by a healthcare provider to minimize the risk of addiction. Can this medicine be taken during pregnancy? Ultracet is classified as FDA Pregnancy Category C for tramadol and Category B for acetaminophen. Animal studies have shown adverse effects on the fetus with tramadol, and there are no adequate and well-controlled studies in pregnant women. Opioids can lead to neonatal opioid withdrawal syndrome when used during pregnancy. Use of Ultracet during pregnancy should be if the potential benefits justify the potential risks to the fetus. Pregnant women should consult their healthcare provider before using Ultracet. Can this medicine be taken while breast-feeding? Both tramadol and acetaminophen are excreted in breast milk. While acetaminophen is considered safe in nursing mothers, tramadol may pose risks to the nursing infant, including sedation and respiratory depression. The decision to use Ultracet while breastfeeding should be made with caution, considering the importance of the medication to the mother and the potential risks to the infant. Nursing mothers should consult with their healthcare provider to discuss the risks and benefits. Uses This product is used to treat moderate to moderately severe pain. It contains 2 medications: tramadol and acetaminophen. Tramadol belongs to a class of drugs known as opioid analgesics. It works in the brain to change how your body feels and responds to pain. Acetaminophen is used to relieve pain, and it can also reduce a fever. How to use Ultracet Read the Medication Guide provided by your pharmacist before you start taking tramadol/acetaminophen and each time you get a refill. If you have any questions, ask your doctor or pharmacist. Take this medication by mouth as directed by your doctor, usually up to every 4 to 6 hours as needed for pain relief. You may take this drug with or without food. If you have nausea, it may help to take this drug with food. Ask your doctor or pharmacist about other ways to decrease nausea (such as lying down for 1 to 2 hours with as little head movement as possible). The dosage is based on your medical condition and response to treatment. To reduce your risk of side effects, your doctor may direct you to start this medication at a low dose and gradually increase your dose. Follow your doctor's instructions carefully. The maximum recommended dose is 8 tablets per day. Do not increase your dose, take the medication more often, or take it for a longer time than prescribed. Properly stop the medication when so directed. Pain medications work best if they are used as the first signs of pain occur. If you wait until the pain has worsened, the medication may not work as well. If you have ongoing pain (such as due to arthritis), your doctor may direct you to also take long-acting opioid medications. In that case, this medication might be used for sudden (breakthrough) pain only as needed. Other pain relievers (such as naproxen, ibuprofen) may also be prescribed. Ask your doctor or pharmacist about using tramadol safely with other drugs. Suddenly stopping this medication may cause withdrawal, especially if you have used it for a long time or in high doses. To prevent withdrawal, your doctor may lower your dose slowly. Tell your doctor or pharmacist right away if you have any withdrawal symptoms such as restlessness, mental/mood changes (including anxiety, trouble sleeping, thoughts of suicide), watering eyes, runny nose, nausea, diarrhea, sweating, muscle aches, or sudden changes in behavior. When this medication is used for a long time, it may not work as well. Talk with your doctor if this medication stops working well. Though it helps many people, this medication may sometimes cause addiction. This risk may be higher if you have a substance use disorder (such as overuse of or addiction to drugs/alcohol). Take this medication exactly as prescribed to lower the risk of addiction. Ask your doctor or pharmacist for more details. Tell your doctor if your pain does not get better or if it gets worse. Warnings Tramadol/acetaminophen has a risk for abuse and addiction, which can lead to overdose and death. Tramadol/acetaminophen may also cause severe, possibly fatal, breathing problems. To lower your risk, your doctor should have you take the smallest dose of tramadol/acetaminophen that works, and take it for the shortest possible time. Ask your doctor or pharmacist if you should have naloxone available to treat opioid overdose. Teach your family or household members about the signs of an opioid overdose and how to treat it. The risk for severe breathing problems is higher when you start this medication and after a dose increase, or if you take the wrong dose/strength. Taking this

medication with alcohol or other drugs that can cause drowsiness or breathing problems may cause very serious side effects, including death. Also, other medications can affect the removal of tramadol/acetaminophen from your body, which may affect how tramadol/acetaminophen works. Be sure you know how to take tramadol/acetaminophen and what other drugs you should avoid taking with it. Get medical help right away if any of these very serious side effects occur: slow/shallow breathing, unusual lightheadedness, severe drowsiness/dizziness, difficulty waking up. Keep this medicine in a safe place to prevent theft, misuse, or abuse. If someone accidentally swallows this drug, get medical help right away. One ingredient in this product is acetaminophen. Taking too much acetaminophen may cause serious (possibly fatal) liver disease. Adults should not take more than 4000 milligrams (4 grams) of acetaminophen a day. People with liver problems and children should take less acetaminophen. Ask your doctor or pharmacist how much acetaminophen is safe to take. Do not use with any other drug containing acetaminophen without asking your doctor or pharmacist first. Acetaminophen is in many nonprescription and prescription medications (such as pain/fever drugs or cough-and-cold products). Check the labels on all your medicines to see if they contain acetaminophen, and ask your pharmacist if you are unsure. Get medical help right away if you take too much acetaminophen (overdose), even if you feel well. Overdose symptoms may include nausea, vomiting, loss of appetite, sweating, stomach/abdominal pain, extreme tiredness, yellowing eyes/skin, and dark urine. Daily alcohol use, especially when combined with acetaminophen, may damage your liver. Avoid alcohol. Before using this medication, women of childbearing age should talk with their doctor(s) about the risks and benefits. Tell your doctor if you are pregnant or if you plan to become pregnant. During pregnancy, this medication should be used only when clearly needed. It may slightly increase the risk of birth defects if used during the first two months of pregnancy. Also, using it for a long time or in high doses near the expected delivery date may harm the unborn baby. To lessen the risk, take the smallest effective dose for the shortest possible time. Babies born to mothers who use this drug for a long time may develop severe (possibly fatal) withdrawal symptoms. Tell the doctor right away if you notice any symptoms in your newborn baby such as crying that doesn't stop, slow/shallow breathing, irritability, shaking, vomiting, diarrhea, poor feeding, or difficulty gaining weight. Children younger than 12 years should not use products that contain tramadol. Children between 12 and 18 years old should not use tramadol after certain surgeries (including tonsil/adenoid removal). Also, tramadol use is not recommended for children between 12 and 18 years old who are obese or have breathing problems. Some children are more sensitive to tramadol and have had very serious (rarely fatal) breathing problems such as slow/shallow breathing. Talk with your doctor or pharmacist about the risks and benefits of this medication. Interactions Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval. Some products that may interact with this drug include: certain pain medications (mixed opioid agonist-antagonists such as butorphanol, nalbuphine, pentazocine), naltrexone, samidorphan. Taking MAO inhibitors with this medication may cause a serious (possibly fatal) drug interaction. Avoid taking MAO inhibitors (isocarboxazid, linezolid, metaxalone, methylene blue, moclobemide, phenelzine, procarbazine, rasagiline, safinamide, selegiline, tranylcypromine) during treatment with this medication. Most MAO inhibitors should also not be taken for two weeks before treatment with this medication. Ask your doctor when to start or stop taking this medication. The risk of serotonin syndrome/toxicity increases if you are also taking other drugs that increase serotonin. Examples include street drugs such as MDMA/"ecstasy," St. John's wort, certain antidepressants (including SSRIs such as fluoxetine/paroxetine, SNRIs such as duloxetine/venlafaxine), among others. The risk of serotonin syndrome/toxicity may be more likely when you start or increase the dose of these drugs. Other medications can affect the removal of tramadol from your body, which may affect how tramadol works. Examples include azole antifungals (such as itraconazole, ketoconazole), levoketoconazole, macrolide antibiotics (such as erythromycin), quinidine, rifamycins (such as rifampin), ritonavir, drugs used to treat seizures (such as carbamazepine), among others. The risk of serious side effects (such as slow/shallow breathing, severe drowsiness/dizziness) may be increased if this medication is taken with other products that may also cause drowsiness or breathing problems. Tell your doctor or pharmacist if you are taking other products such as other opioid pain or cough relievers (such as codeine, hydrocodone), alcohol, marijuana (cannabis), drugs for sleep or anxiety (such as alprazolam, lorazepam, zolpidem), muscle

relaxants (such as carisoprodol, cyclobenzaprine), or antihistamines (such as cetirizine, diphenhydramine). Check the labels on all your medicines (such as allergy or cough-and-cold products) because they may contain ingredients that cause drowsiness. Ask your pharmacist about using those products safely. This medication may interfere with certain lab tests (such as amylase/lipase levels), possibly causing false test results. Make sure lab personnel and all your doctors know you use this drug.

Precautions Before taking this product, tell your doctor or pharmacist if you are allergic to tramadol or acetaminophen; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. Before using this medication, tell your doctor or pharmacist your medical history, especially of: brain disorders (such as head injury, tumor, seizures), breathing problems (such as asthma, sleep apnea, chronic obstructive pulmonary disease-COPD), kidney disease, liver disease, diabetes, mental/mood disorders (such as confusion, depression, suicidal thoughts), personal or family history of a substance use disorder (such as overuse of or addiction to drugs/alcohol), stomach/intestinal problems (such as blockage, constipation, diarrhea due to infection, paralytic ileus), difficulty urinating (such as due to enlarged prostate), gallbladder disease, disease of the pancreas (pancreatitis), obesity. This drug may make you dizzy or drowsy. Alcohol or marijuana (cannabis) can make you more dizzy or drowsy. Do not drive, use machinery, or do anything that needs alertness until you can do it safely. Avoid alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis).

Tramadol/acetaminophen may cause a condition that affects the heart rhythm (QT prolongation). QT prolongation can rarely cause serious (rarely fatal) fast/irregular heartbeat and other symptoms (such as severe dizziness, fainting) that need medical attention right away. The risk of QT prolongation may be increased if you have certain medical conditions or are taking other drugs that may cause QT prolongation. Before using tramadol/acetaminophen, tell your doctor or pharmacist of all the drugs you take and if you have any of the following conditions: certain heart problems (heart failure, slow heartbeat, QT prolongation in the EKG), family history of certain heart problems (QT prolongation in the EKG, sudden cardiac death). Low levels of potassium or magnesium in the blood may also increase your risk of QT prolongation. This risk may increase if you use certain drugs (such as diuretics/"water pills") or if you have conditions such as severe sweating, diarrhea, or vomiting. Talk to your doctor about using tramadol/acetaminophen safely. Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). Some children may be more sensitive to very serious side effects of tramadol, such as extreme sleepiness, confusion, or slow/shallow/noisy breathing. () Older adults may be more sensitive to the side effects of this drug, especially confusion, dizziness, drowsiness, slow/shallow breathing, and QT prolongation (see above). Older adults may also be more likely to develop a type of salt imbalance (hyponatremia) while using this drug. During pregnancy, this medication should be used only when clearly needed. It may harm an unborn baby. Discuss the risks and benefits with your doctor. () This medication passes into breast milk and may have undesirable effects on a nursing infant, such as unusual sleepiness, difficulty feeding, or trouble breathing. Breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

Overdose If someone has overdosed and has serious symptoms such as passing out or trouble breathing, give them naloxone if available, then call 911. If the person is awake and has no symptoms, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include: slow/shallow breathing, nausea, vomiting, loss of appetite, sweating, slow/irregular heartbeat, stomach/abdominal pain, extreme tiredness, yellowing eyes/skin, dark urine, seizure, coma. Do not share this medication with others. Sharing it is against the law. This medication has been prescribed for your current condition only. Do not use it later for another condition unless told to do so by your doctor. A different medication may be necessary in that case. Not applicable. Store at room temperature away from light and moisture. Keep all medications away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

Side Effects

Uses

Interactions

Other Details
