Medication Guide
ULTRACET® [UHL-truh-set]
(tramadol hydrochloride/acetaminophen)
Tablets, CIV

ULTRACET is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used for the short-term (five days or less) management of acute pain, when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.

Important information about ULTRACET:

- **Get emergency help right away if you take too much ULTRACET (overdose)**. When you first start taking ULTRACET, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur.
- ULTRACET can cause severe drowsiness, breathing problems (respiratory depression), coma and death when taken with benzodiazepines or other medicines that depress consciousness.
- Never give anyone else your ULTRACET. They could die from taking it. Store ULTRACET away from children and in a safe place to prevent stealing or abuse. Selling or giving away ULTRACET is against the law.
- Get emergency help right away if you take more than 4,000 mg of acetaminophen in 1 day. Taking ULTRACET with other products that contain acetaminophen can lead to serious liver problems and death.

Do not take ULTRACET if you have:

- Severe asthma, trouble breathing, or other lung problems.
- A bowel blockage or have narrowing of the stomach or intestines.
- An allergy to any of its ingredients (e.g., tramadol hydrochloride or acetaminophen).
- Taken a Monoamine Oxidase Inhibitor, MAOI, (medicine used for depression) within the last 14 days.

Before taking ULTRACET, tell your healthcare provider if you have a history of:

- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** Prolonged use of ULTRACET during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** ULTRACET passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking ULTRACET with certain other medicines can cause serious side effects that could lead to death.

When taking ULTRACET:

- Do not change your dose. Take ULTRACET exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Take your prescribed dose: 2 tablets every 4 to 6 hours as needed for pain relief for a maximum of 5 days. Do not take more than your prescribed dose and do not take more than 8 tablets per day. If you miss a dose, take your next dose at your usual time.
- Call your healthcare provider if the dose you are taking does not control your pain.
- If you have been taking ULTRACET regularly, do not stop taking ULTRACET without talking to your healthcare provider.

- After you stop taking ULTRACET, ask your pharmacist how to dispose of any unused tablets.

While taking ULTRACET DO NOT:

- Drive or operate heavy machinery, until you know how ULTRACET affects you. ULTRACET can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with ULTRACET may cause you to overdose and die.

The possible side effects of ULTRACET:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

These are not all the possible side effects of ULTRACET. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov**

Manufactured by: Janssen Ortho, LLC, Gurabo, Puerto Rico 00778. Manufactured for: Janssen Pharmaceuticals, Inc. Titusville, New Jersey 08560**,** 1-800-526-7736.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Issued: 12/2016