

REVIEWED

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Ultram
(tramadol hydrochloride)

THERAPEUTIC CLASS

Centrally acting analgesic

DEA CLASS

CIV

ADULT DOSAGE & INDICATIONS

Moderate to Moderately Severe Pain

≥17 Years:

Initial: 25mg/day qam

Titrate: Increase in 25mg increments every 3 days to reach 100mg/day (25mg qid), then may increase total daily dose by 50mg as tolerated every 3 days to reach 200mg/day (50mg qid)

After Titration/Rapid Onset Required: 50-100mg q4-6h prn

Max: 400mg/day

DOSING CONSIDERATIONS

Renal Impairment

CrCl <30mL/min:

Increase dosing interval to 12 hrs

Dialysis patients may receive regular dose on the day of dialysis

Max: 200mg/day

Hepatic Impairment

Cirrhosis: 50mg q12h

Elderly

Start at lower end of dosing range

>75 Years:

Max: 300mg/day

ADMINISTRATION

Oral route

Administer w/o regard to food

HOW SUPPLIED

Tab: 50mg* *scored

CONTRAINDICATIONS

Any situation where opioids are contraindicated, including acute intoxication with alcohol, hypnotics, narcotics, centrally acting analgesics, opioids, or psychotropic drugs.

WARNINGS/PRECAUTIONS

Do not exceed recommended dose. Seizures reported; risk increases in patients with epilepsy, history of seizures, recognized risk for seizures, and with naloxone coadministration. Anaphylactoid reactions and potentially life-threatening serotonin syndrome may occur. Avoid in patients who are suicidal or addiction-prone, and with history of anaphylactoid reactions to codeine and other opioids. Caution with emotional disturbances or depression, and in elderly. Tramadol-related deaths reported with previous histories of emotional disturbances, suicidal ideation/attempts, and misuse of tranquilizers, alcohol, and other CNS active drugs. Caution in patients at risk for respiratory depression; consider alternative nonopioid analgesics. Caution with increased intracranial pressure (ICP) or head injury. May impair mental/physical abilities. Withdrawal symptoms may occur if discontinued abruptly. May complicate clinical assessment of acute abdominal conditions. Not for use in pregnant women prior to or during labor unless benefits outweigh risks. Not recommended for obstetrical preoperative medication or for postdelivery analgesia in nursing mothers.

ADVERSE REACTIONS

Dizziness/vertigo, N/V, constipation, headache, somnolence, sweating, asthenia, dyspepsia, dry mouth, diarrhea, pruritus.

DRUG INTERACTIONS

See Contraindications. Caution and reduce dose with CNS depressants (eg, alcohol, opioids, anesthetics); increased risk of CNS/respiratory depression. CYP2D6 inhibitors (eg, quinidine, fluoxetine, paroxetine, amitriptyline) and CYP3A4 inhibitors (eg, ketoconazole, erythromycin) may reduce metabolic clearance and increase risk for serious adverse events including seizures and serotonin syndrome. Altered exposure with CYP3A4 inducers (eg, rifampin, St. John's wort). Increased seizure risk with SSRIs, TCAs, other tricyclic compounds (eg, cyclobenzaprine, promethazine), MAOIs, other opioids, neuroleptics, and drugs that reduce seizure threshold. Caution with SSRIs, SNRIs, TCAs, MAOIs, α 2-adrenergic blockers, triptans, linezolid, lithium, St. John's wort, and drugs that impair tramadol metabolism, due to potential serotonin syndrome. Not recommended with carbamazepine; may significantly reduce analgesic effect. Digoxin toxicity and alteration of warfarin effect, including elevation of PT, reported rarely.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

Centrally acting synthetic opioid analgesic; has not been established. Suspected to be due to binding of parent and (O-desmethyltramadol) M1 metabolite to μ -opioid receptors and weak inhibition of norepinephrine and serotonin reuptake.

PHARMACOKINETICS

Absorption: Absolute bioavailability (75%, 100mg). Administration of multiple doses resulted in different parameters. **Distribution:** (100mg IV) $V_d=2.6L/kg$ (male), $2.9L/kg$ (female); plasma protein binding (20%); found in breast milk (IV); crosses placenta. **Metabolism:** Extensive via CYP2D6, 3A4 and 2B6; N- and O-demethylation and glucuronidation or sulfation (major pathway); M1 (active metabolite). **Elimination:** Urine (30% unchanged, 60% as metabolites); $T_{1/2}=6.3$ hrs, 7.4 hrs (M1).

ASSESSMENT

Assess for previous hypersensitivity to the drug and other opioids, acute intoxication with alcohol/hypnotics/narcotics/centrally acting analgesics/opioids/psychotropic drugs, epilepsy, seizure and respiratory depression risks, suicidal ideation, emotional disturbance or depression, increased ICP, head injury, drug abuse potential, suicidal/addiction proneness, pain severity, renal/hepatic impairment, pregnancy/nursing status, any other conditions where treatment is contraindicated or cautioned, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of anaphylactoid reactions, respiratory/CNS depression, tolerance, physical dependence, seizures, serotonin syndrome, withdrawal symptoms, and other adverse reactions.

PATIENT COUNSELING

Inform of the risks and benefits of therapy. Inform that drug may cause seizures and/or serotonin syndrome with concomitant use of serotonergic agents or drugs that significantly reduce the metabolic clearance of therapy. Inform that drug may impair physical/mental abilities required for the performance of hazardous tasks (eg, driving a car, operating machinery). Instruct not to take drug with alcohol containing beverages. Inform to use drug with caution when taking tranquilizers, hypnotics, other opiate containing analgesics). Instruct to inform physician if pregnant, think or trying to become pregnant. Educate about single-dose and 24-hr dose limits and time interval between doses; advise not to exceed the recommended dose.

STORAGE

25°C (77°F); excursions permitted to 15-30°C (59-86°F).