Name(s)

- **Generic:** tramadol (TRA ma dole) | **Brand:** Ultram, Qdolo, ConZip

Therapeutic Category

- Analgesic, Opioid

Dosage Form & Strength

- **Tablet:** 50 mg, 100 mg | **ER Tablet:** 100 mg, 200 mg, 300 mg | **Solution:** 5 mg/mL | **ER Capsule:** 100 mg, 150 mg, 200 mg, 300 mg

Indication(s)

1. **Pain Mangement:** IR and ER tablets are used to manage chronic severe pain when alternative options are inadequate. Tramadol is reserved when nonopioid alternatives are not tolerated or ineffective. Important to note that ER tramadol is **not indicated** for prn use and lowest effective dose is used.

- OFF LABEL | Premature ejaculation and refractory restless leg syndrome (RLS)

Dosing by Indication

1. Adults | **Pain Mangement:** Moderate to severe
    - **Acute pain**: Initiate 50 mg po q 4-6 h prn. Alternate dosing is 25-50 mg po tid. Max dosing is 50-100 mg po q 4-6 h with a max of 400 mg per day.
    - **Chronic pain:** IR tablets are initiated 25-50 mg q 6 h prn (at <300 mg per day). If required, dose increase up to 50-100 mg po q 4-6 h with a max of 400 mg per day. | ER tablets are initiated at 100 mg po qd and may increase up to 100 mg/day every 5 days up to 300 mg per day.
- OFF LABEL | Premature ejaculation (25-50 mg 1-3 hours prior to sexual activity); RLS (50-100 mg qhs)
- Pediatric | Pain Management: Moderate to severe (Limited data. Refer to most current literature)
    - **Acute pain:** 4 - ≤16 years (1-2 mg/kg/dose q 4-6 h); Adolescents ≥17 years (25-100 mg q 4-6 h titrating q 3 days up to lowest effective dose; max 400 mg/day)
    - **Chronic pain:** Adolescents ≥18 years (100 mg qd titrating q 5 days up to lowest effective dose; max 300 mg/day)

Mechanism of Action & Pharmacology

- Tramadol as both the drug and as the active metabolite binds to the mu-opiate receptor. By binding to the mu-opiate receptor blocks the ascending pain pathways as well as altering the response and perception to pain. Tramadol also blocks reuptake of both serotonin (5HT) and norepinephrine (NE) which plays an important role in the descending inhibitory pain pathway.
- **Metabolized** extensively hepatically via the CYP3A4 and CYP2D6. The CYP2D6 pathway results in an active metabolite (M1). | **Excreted** in the urine with 30% as unchanged drug and 60% as metabolites. The **Onset of Action** for the immediate release formulation is w/in 1 hour with a peak effect between 2-3 hours. | The **Half-Life Elimination** for the IR form is ~6.3 hours with the active metabolite (M1) ~7.4 hours. The ER formulation is ~8-10 hour and the metabolite ~9-11 hours. | Tramadol is poorly **protein bound** at ~20% in the plasma.

Special Populations & Considerations

- **Renal Impairment:** ↓ Excretion | **Hepatic Impairment:** ↑ AUC, ↑ elimination half-life | **Elderly:** ↑ Serum concentration, ↑ elimination half-life | **Gender**: Women have 12% higher peak concentration and 35% higher AUC when compared to men | **Poor metabolizer:** ↑ concentrations of drug (20%) and ↓ metabolite (40%) | **Discontinuation of therapy:** Gradually taper down to minimize withdrawl.

Side Effects

- **General: Nausea**, vomiting, constipation, lightheadedness, dizziness, drowsiness, & headache.
- **Major Concern:** Serotonin syndrome (agitation, abnormal heartbeat, severe n/v/d), QT prolongation| **Pregnancy:** Crosses placenta. Not commonly used to treat pain during pregnancy.

BLACK BOX WARNING: Addiction/abuse/misuse – Opioid addiction in which overdose may lead to death. **Risk of medication errors –** mg and mL confusion w/ prescribing/dispensing/administering solution. **Life-threatening respiratory depression –** Serious/fatal/life-treatening respiratory depression may cause death. **Accidential ingestion –** Can be fatal in children. **Ultra-rapid metabolizer in chidren (CYP450 2D6 polymorphism) –** Avoid use in children <12 years and <18 years that may have increased sensitivity. **Opioid analgesic REMS; Interactions w/ drugs affecting CYP P450 isoenzymes; Neonatal opioid w/d syndrome (use during pregnancy); Contaminant use w/ benzodiazepines or other CNS depressants.**

Drug Interactions

- **General:** MOAIs, mixed opioid agonist-antagonists, amphetamines, anticholinergic agents & CNS depressants (↑effects), serotonin affecting substances (such as antiemetics & antidepressants), CYP2D6 inhibitors (↓active metabolite), CYP2D6 inducers (↑active metabolite), CYP3A4 inducers (↓drug serum concentrations), CYP3A4 inhibitors (↑drug serum concentrations), and hypoglycemia-associated agents (↑hypoglycemic effects)

Monitoring Parameters

- Level of pain relief; Respiratory status; EKG & Heart rate (especially if family hx); Bowel function; Suicidal behavior/ideation; Addiction/abuse/misuse; & Pregnancy.

Patient Counseling Information

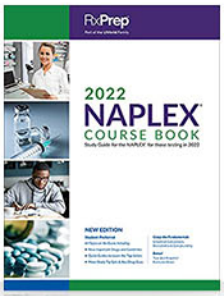
- Tramadol is used to ease pain. | Generally “minor” side effects are experienced such as dizziness, n/v/d, & headache.

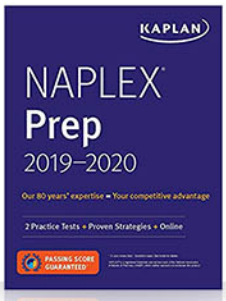
Reference(s)

- https://www.drugs.com/ppa/tramadol.html
- https://www.webmd.com/drugs/2/drug-4398-5239/tramadol-oral/tramadol-oral/details

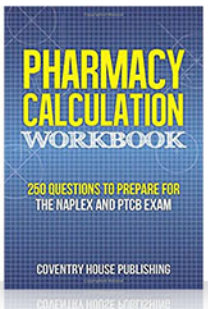
PREPARE FOR SUCCESS!

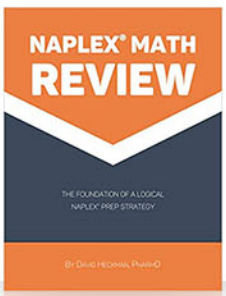
Comprehensive (NAPLEX)

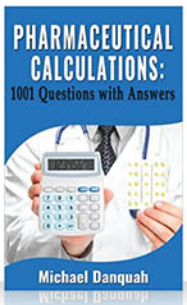


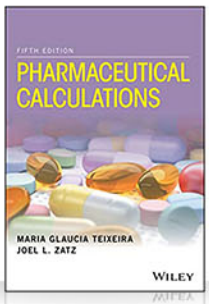


Calculations (NAPLEX)

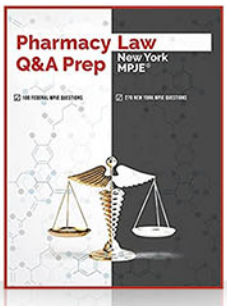


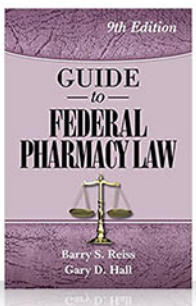




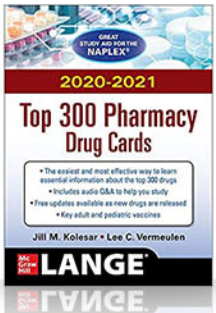


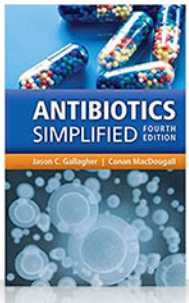
Pharmacy Law (MPJE)

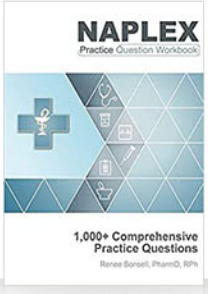


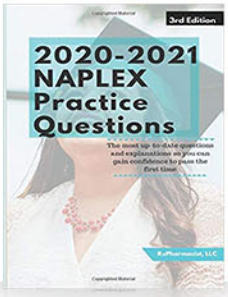


Supplemental









DISCLAIMERS

DRUG CARDS DAILY

Monday at 7 am EST
(6 am CST, 4 am PST)

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This helps focus your learning and the repetition helps to retain info and indirectly prepare you for the NAPLEX

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