Nucynta (tapentadol) - Drug Summary

Janssen Pharmaceuticals, Inc.

Jump to Section
- THERAPEUTIC CLASS
- DEA CLASS
- ADULT DOSAGE & INDICATIONS
- DOSING CONSIDERATIONS
- ADMINISTRATION
- ▼ *View All Sections...*

Related Drug Information ▼

Nucynta (tapentadol)

THERAPEUTIC CLASS

Centrally acting analgesic

DEA CLASS

CII

ADULT DOSAGE & INDICATIONS

Acute Pain

Moderate to Severe:
Usual: 50mg, 75mg, or 100mg q4-6h depending upon pain intensity
Day 1: May give 2nd dose 1 hr after 1st dose if pain relief is inadequate, then 50mg, 75mg, or 100mg q4-6h
Adjust dose to maintain adequate analgesia w/ acceptable tolerability
Max: 700mg on Day 1, then 600mg/day thereafter

Periodically reassess continued need for use during chronic therapy, especially for noncancer-related pain

DOSING CONSIDERATIONS

Hepatic Impairment
Moderate (Child-Pugh Score 7-9):
Initial: 50mg no more frequently than once q8h
Max: 3 doses/24 hrs

Elderly
Start at lower end of dosing range

Discontinuation
Taper dose gradually

ADMINISTRATION

Oral route

Take w/ or w/o food

HOW SUPPLIED

Tab: 50mg, 75mg, 100mg

CONTRAINDICATIONS

Significant respiratory depression, acute or severe bronchial asthma or hypercarbia in an unmonitored setting or in the absence of resuscitative equipment, known or suspected paralytic ileus, and patients receiving MAOIs or who have taken them within the last 14 days. Hypersensitivity (eg, anaphylaxis, angioedema) to tapentadol or to any other ingredients of the product.

WARNINGS/PRECAUTIONS

Abuse liability similar to other opioid agonists legal or illicit; assess each patient's risk for opioid abuse or addiction prior to prescribing. Routinely monitor all patients for signs of misuse, abuse, and addiction; misuse or abuse by crushing, chewing, snorting, or injecting will pose a significant risk that could result in overdose and death. Respiratory depression, if not immediately recognized and treated, may lead to respiratory arrest and death. Accidental ingestion, especially in children, can result in fatal overdose. Respiratory depression is more likely to occur in elderly, cachectic, or debilitated patients; monitor closely, particularly when given with drugs that depress respiration. Monitor for respiratory depression and consider use of alternative nonopioid analgesics in patients with significant COPD or cor pulmonale, and in patients with a substantially decreased respiratory reserve, hypoxia, hypercarbia, or preexisting respiratory depression. May cause severe hypotension. Monitor for signs of sedation and respiratory depression in patients susceptible to the intracranial effects of carbon dioxide retention (eg, those with evidence of increased intracranial pressure or brain tumors). May obscure clinical course in patients with a head injury. Avoid with circulatory shock, impaired consciousness, or coma. May aggravate convulsions in patients with convulsive disorders and may induce or aggravate seizures; monitor for worsened seizure control in patients with history of seizure disorders. May cause spasm of sphincter of Oddi; monitor for worsening symptoms in patients with biliary tract disease (eg, acute pancreatitis). Withdrawal symptoms may occur if discontinued abruptly. May impair mental/physical abilities. Monitor for respiratory/CNS depression with moderate hepatic impairment. Avoid use with severe renal/hepatic impairment. Not for use during and immediately prior to labor.

ADVERSE REACTIONS

N/V, dizziness, somnolence, constipation, pruritus, dry mouth, hyperhidrosis, fatigue.

DRUG INTERACTIONS

See Contraindications. Avoid use with alcoholic beverages or medications containing alcohol, other opioids, or drugs of abuse; may have additive effects. CNS depressants (eg, sedatives or hypnotics, general anesthetics, phenothiazines, tranquilizers, alcohol, anxiolytics, neuroleptics, muscle relaxants, other opioids, illicit drugs) may increase risk of respiratory depression, hypotension, profound sedation, or coma; start tapentadol at 1/3 to 1/2 of the usual dose and consider using a lower dose of concomitant CNS depressant. Serotonin syndrome may occur with serotonergic drugs (eg, SSRIs, SNRIs, TCAs, triptans, drugs that affect the serotonergic neurotransmitter system [eg, mirtazapine, trazodone, tramadol]), and drugs that may impair metabolism of serotonin (eg, MAOIs); use with caution. Avoid use with mixed agonist/antagonist analgesics (eg, butorphanol, nalbuphine, pentazocine), and partial agonists (eg, buprenorphine); may precipitate withdrawal symptoms. Anticholinergics may increase risk of urinary retention and/or severe constipation, which may lead to paralytic ileus.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

Centrally acting synthetic analgesic; not established. Suspected to be due to μ-opioid agonist activity and the inhibition of norepinephrine reuptake.

PHARMACOKINETICS

Absorption: T_{max}=1.25 hrs; absolute bioavailability (32%). **Distribution:** (IV) V_d=540L; plasma protein binding (20%); crosses placenta. **Metabolism:** Conjugation; N-desmethyl tapentadol by CYP2C9 and CYP2C19; hydroxy tapentadol by CYP2D6. **Elimination:** Kidneys (99%); urine (3% unchanged, 70% conjugated); $T_{1/2}$=4 hrs.

ASSESSMENT

Assess for personal/family history or risk factors for drug abuse or addiction, general condition and medical status, opioid experience/tolerance, pain type/severity, previous opioid daily dose, potency and type of prior analgesics used, respiratory depression, COPD or other respiratory complications, GI obstruction, paralytic ileus, renal/hepatic impairment, pregnancy/nursing status, possible drug interactions, and any other condition where treatment is contraindicated or cautioned.

MONITORING

Monitor for improvement of pain, signs/symptoms of respiratory depression, hypotension, symptoms of worsening biliary tract disease, aggravation/induction of seizure, tolerance, physical dependence, mental/physical impairment, serotonin syndrome, and other adverse reactions. Routinely monitor for signs of misuse, abuse, and addiction. Periodically reassess continued need for use during chronic therapy, especially for noncancer-related pain.

PATIENT COUNSELING

Instruct to take only as prescribed and not to d/c without first discussing the need for a tapering regimen with prescriber. Inform that drug has potential for abuse; instruct not to share drug with others and to take steps to protect from theft or misuse. Discuss the risks of respiratory depression, orthostatic hypotension, syncope, severe constipation, and anaphylaxis; counsel on how to recognize symptoms and when to seek medical attention. Inform that accidental exposure may result in serious harm or death; advise to dispose unused tabs by flushing them down the toilet. Inform about risks of concomitant use of alcohol, other CNS depressants, MAOIs, and serotonergic drugs; instruct to notify physician if taking/planning to take additional medications. Instruct to not consume alcoholic beverages, or take prescription and OTC products that contain alcohol, during treatment. Counsel that drug may cause seizures if at risk for seizures or if patient has epilepsy; advise to d/c therapy and seek medical attention if seizures occur during therapy. Inform that drug may impair the ability to perform potentially hazardous activities (eg, driving a car or operating heavy machinery); advise not to perform such tasks until patients know how they will react to the medication. Advise females that drug can cause fetal harm; instruct to notify physician if pregnant/planning to become pregnant.

STORAGE

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

Back to top