Butorphanol Tartrate Nasal Solution (butorphanol tartrate) - Drug Summary

Mylan Pharmaceuticals Inc.

Related Drug Information ▼

Butorphanol Spray (butorphanol tartrate)

COMMON BRAND NAMES

Stadol (Discontinued), Butorphanol Spray

THERAPEUTIC CLASS

Partial opioid agonist

DEA CLASS

CIV

ADULT DOSAGE & INDICATIONS

Pain

Initial: 1mg (1 spray in 1 nostril); if adequate pain relief is not achieved w/in 60-90 min, an additional 1mg dose may be given

Sequence may be repeated in 3-4 hrs as required after the 2nd dose of the sequence

Depending on severity of pain, 2mg (1 spray in each nostril) may be used initially in patients able to remain recumbent in the event of drowsiness or dizziness; single additional 2mg doses should not be given for 3-4 hrs

DOSING CONSIDERATIONS

Elderly
Initial dose sequence should be limited to 1mg followed, if needed, by 1mg in 90-120 min
Repeat dose sequence should be determined by patient's response at intervals ≥6 hrs

Renal Impairment
Initial dose sequence should be limited to 1mg followed, if needed, by 1mg in 90-120 min
Repeat dose sequence should be determined by patient's response at intervals ≥6 hrs

Hepatic Impairment
Initial dose sequence should be limited to 1mg followed, if needed, by 1mg in 90-120 min
Repeat dose sequence should be determined by patient's response at intervals ≥6 hrs

ADMINISTRATION

Intranasal route

Disposal
Dispose unit by unscrewing cap, rinsing bottle, and placing parts in a waste container

HOW SUPPLIED

Nasal Spray: 10mg/mL [2.5mL]

CONTRAINDICATIONS

Hypersensitivity to butorphanol tartrate or to benzethonium chloride.

WARNINGS/PRECAUTIONS

Not recommended for use in narcotic-dependent patients. Chronic use may precipitate withdrawal symptoms (eg, anxiety, agitation, mood changes, hallucinations, dysphoria, weakness, diarrhea). Caution with patients who

have recently received repeated doses of narcotic analgesic medication. Episodes of abuse reported. May develop tolerance or physical dependence during prolonged, continuous use; abrupt d/c may result in withdrawal symptoms. Hypotension associated with syncope during the 1st hour of dosing reported rarely; avoid activities with potential risks. Caution with head injury, increased intracranial pressure, acute myocardial infarction (AMI), ventricular dysfunction, or coronary insufficiency; use only if benefits of use outweigh risks. Severe HTN reported; d/c if occurs. May impair mental/physical abilities. May produce respiratory depression especially in patients with CNS disease or respiratory impairment. Caution in elderly, hepatic, and renal impairment. Not recommended for use in induction or maintenance of anesthesia, and in labor.

ADVERSE REACTIONS

Somnolence, dizziness, N/V, nasal congestion, insomnia.

DRUG INTERACTIONS

Increased CNS depression with CNS depressants (eg, alcohol, barbiturates, tranquilizers, antihistamines); use smallest effective dose and reduced frequency of dosing. Diminished analgesic effect if administered shortly after sumatriptan nasal solution. Effects of other concomitant medications that affect hepatic metabolism of drugs (eg, erythromycin, theophylline) not known; smaller initial dose and longer intervals between doses may be needed. Decreased absorption rate with nasal vasoconstrictors (eg, oxymetazoline).

PREGNANCY AND LACTATION

Category C, caution in nursing.

MECHANISM OF ACTION

Opioid agonist-antagonist analgesic; has low intrinsic activity at receptors of μ-opioid type (morphine-like) and agonist at k-opioid receptors.

PHARMACOKINETICS

Absorption: Absolute bioavailability (60-70%); C_{max}=0.9-1.04ng/mL; T_{max}=30-60 min. Parameters in elderly differ from younger, refer to PI. **Distribution:** V_d=305-901L; plasma protein binding (80%); crosses placental barriers, found in breast milk. **Metabolism:** Liver; Hydroxybutorphanol (major metabolite). **Elimination:** Urine (5% unchanged, 49% hydroxybutorphanol, <5% norbutorphanol), feces; $T_{1/2}$=18 hrs (hydroxybutorphanol).

ASSESSMENT

Assess for hypersensitivity, head injury, elevated intracranial pressure, narcotic dependence, respiratory impairment, AMI, ventricular dysfunction or coronary insufficiency, CNS diseases, hepatic/renal impairment, pregnancy/nursing status, and possible drug interactions. Assess for age, weight, physical status, underlying pathologic condition, type of anesthesia, and surgical procedure involved.

MONITORING

Monitor for signs/symptoms of drug abuse/dependence/tolerance, hypotension, HTN, respiratory depression, withdrawal symptoms, and other adverse reactions.

PATIENT COUNSELING

Inform that medication may impair physical/mental abilities; do not perform dangerous tasks (eg, operating machinery/driving) for at least 1 hr or until drug effects are no longer present. Instruct to avoid alcohol during medication and inform that use of drugs affecting the CNS may result in increased depressant effects such as drowsiness, dizziness, and impaired mental function. Counsel that therapy has the potential for abuse and should be handled accordingly. Instruct on the proper use of nasal solution.

STORAGE

15-30°C (59-86°F).

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