Buprenorphine Hydrochloride (buprenorphine hydrochloride) - Drug Summary

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Related Drug Information

Buprenorphine (buprenorphine hydrochloride)

COMMON BRAND NAMES

Subutex (Discontinued), Buprenorphine

THERAPEUTIC CLASS

Partial opioid agonist

DEA CLASS

CIII

ADULT DOSAGE & INDICATIONS

Opioid Dependence

Used as part of a complete treatment plan to include counseling and psychosocial support

Administer SL as single daily dose

Before Induction:
Consider type/degree/level of opioid dependence and time since last opioid use

Induction:
Titrate to clinical effectiveness as rapidly as possible
On Heroin/Other Short-Acting Opioids:
Administer at least 4 hrs after last opioid use or preferably, when moderate signs of opioid withdrawal appear
On Methadone/Other Long-Acting Opioids:
Initiate when moderate signs of opioid withdrawal appear

Maint (Unable to Tolerate Presence of Naloxone):
Adjust dose progressively in increments/decrements of 2mg or 4mg
Maint Dose Range: 4-24mg/day

DOSING CONSIDERATIONS

Hepatic Impairment
Severe: Consider reducing starting and titration dose by 1/2

Elderly
Start at low end of dosing range

Discontinuation
Decision to d/c after a period of maint should be made as part of a comprehensive treatment plan

ADMINISTRATION

SL route

Do not chew or swallow; SL tab should be placed under tongue until dissolved
For doses requiring use of more than 2 tabs, place all tabs at once or alternatively (if they cannot fit in more than 2 tabs comfortably), place 2 tabs at a time under tongue

HOW SUPPLIED

Tab, SL: 2mg, 8mg

WARNINGS/PRECAUTIONS

Potential for abuse. Significant respiratory depression reported; caution with compromised respiratory function. To manage overdose, higher than normal doses and repeated administration of naloxone may be necessary. Accidental pediatric exposure can cause severe/fatal respiratory depression. Chronic use produces dependence of the opioid type. Cytolytic hepatitis and hepatitis with jaundice reported. If a hepatic event is suspected, biological and etiological evaluation is recommended. D/C therapy carefully to prevent withdrawal signs/symptoms and a return to illicit drug use; strictly monitor patient. Caution with preexisting liver enzyme abnormalities, hepatitis B or C infection, use with other potentially hepatotoxic drugs, and ongoing injecting drug use. Hypersensitivity reactions, bronchospasm, angioneurotic edema, and anaphylactic shock reported. May precipitate opioid withdrawal signs and symptoms if administered before the agonist effects of the opioid have subsided. Neonatal withdrawal reported when used during pregnancy. Not appropriate as an analgesic. May impair physical/mental abilities. May produce orthostatic hypotension in ambulatory patients. May elevate CSF pressure; caution with head injury, intracranial lesions, and other circumstances when cerebrospinal pressure may be increased. May produce miosis and changes in level of consciousness that may interfere with patient evaluation. May increase intracholedochal pressure; caution with biliary tract dysfunction. May obscure diagnosis or clinical course of patients with acute abdominal conditions. Caution with myxedema or hypothyroidism, adrenal cortical insufficiency (eg, Addison's disease), CNS depression or coma, toxic psychoses, prostatic hypertrophy, urethral stricture, acute alcoholism, delirium tremens, kyphoscoliosis, moderate/severe hepatic impairment, and in the debilitated/elderly.

ADVERSE REACTIONS

Headache, pain, withdrawal syndrome, vasodilation, infection, abdominal pain, asthenia, back pain, N/V, anxiety, constipation, insomnia, rhinitis, sweating, depression.

DRUG INTERACTIONS

May cause respiratory depression, coma, and death with benzodiazepines or other CNS depressants (eg, alcohol); caution when used concurrently. May cause increased CNS depression with general anesthetics, benzodiazepines, or other CNS depressants (eg, alcohol); consider dose reduction of 1 or both agents. Concomitant use with CYP3A4 inhibitors (eg, azole antifungals, macrolides, HIV protease inhibitors) should be monitored and may require dose reduction of 1 or both agents. Monitor for signs and symptoms of opioid withdrawal with CYP3A4 inducers (eg, phenobarbital, carbamazepine, phenytoin). Monitor dose if non-nucleoside reverse transcriptase inhibitors are added to treatment regimen. Atazanavir and atazanavir/ritonavir may increase levels; monitor and consider dose reduction of buprenorphine.

PREGNANCY AND LACTATION

Category C, caution in nursing.

MECHANISM OF ACTION

Partial opioid agonist/opioid antagonist; partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor.

PHARMACOKINETICS

Absorption: Administration of variable doses resulted in different parameters. **Distribution:** Plasma protein binding (96%); found in breast milk. **Metabolism:** Liver (extensive); N-dealkylation (by CYP3A4) and glucuronidation pathways; norbuprenorphine (major metabolite). **Elimination:** Urine (30%), feces (69%); $T_{1/2}$=31-35 hrs.

ASSESSMENT

Assess for history of hypersensitivity reactions, debilitation, myxedema, hypothyroidism, acute alcoholism, adrenal cortical insufficiency (eg, Addison's disease), CNS depression or coma, toxic psychoses, prostatic hypertrophy, urethral stricture, delirium tremens, kyphoscoliosis, biliary tract dysfunction, hepatic impairment, compromised respiratory function, hepatitis B or C infection, head injury, intracranial lesions and other circumstances in which CSF pressure may be increased, acute abdominal conditions, pregnancy/nursing status, and possible drug interactions. Perform LFTs prior to therapy.

MONITORING

Monitor for hypersensitivity reactions, signs/symptoms of opioid withdrawal, impaired mental/physical ability, orthostatic hypotension, respiratory depression, drug abuse/dependence, hepatitis, hepatic events, elevation of CSF, miosis, changes in consciousness levels, and other adverse reactions. Monitor LFTs periodically. Closely monitor neonates for signs of respiratory depression if the mother received the drug prior to delivery.

PATIENT COUNSELING

Warn patient on the dangers of self-administration of benzodiazepines and other CNS depressants, including alcohol, while on therapy. Inform that tab contains an opioid that can be a target for abuse; instruct to keep tabs in safe place protected from theft and children. Instruct to seek medical attention immediately if a child is exposed to the drug. Inform that treatment may impair physical/mental abilities and cause orthostatic hypotension. Instruct to take tab qd and not to change dose without consulting physician. Inform that treatment can cause dependence and withdrawal signs and symptoms may occur upon discontinuation. Advise patients seeking to d/c treatment with buprenorphine for opioid dependence to work closely with physician on a tapering schedule, and apprise of the potential to relapse to illicit drug use associated with discontinuation of treatment. Instruct to report to physician all medications prescribed or currently being used. Inform women

regarding possible effects during pregnancy and not to breastfeed. Advise to dispose of unused drugs as soon as they are no longer needed by flushing the tabs down the toilet. Instruct family members to, in the event of emergency, notify physician or emergency room staff that patient is physically dependent on an opioid and is being treated with buprenorphine SL tab.

STORAGE

20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F).

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