Trezix (acetaminophen/caffeine/dihydrocodeine bitartrate) - Drug Summary

WraSer Pharmaceuticals

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

Related Drug Information ▼

Trezix (acetaminophen/caffeine/dihydrocodeine bitartrate)

BOXED WARNING

Respiratory depression and death have occurred in children who received codeine following tonsillectomy and/or adenoidectomy and had evidence of being ultra-rapid metabolizers of codeine due to a CYP2D6 polymorphism. Acetaminophen (APAP) has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most cases of liver injury are associated with APAP use at doses >4000mg/day, and often involve >1 APAP-containing product.

THERAPEUTIC CLASS

Opioid analgesic

DEA CLASS

CIII

ADULT DOSAGE & INDICATIONS

Moderate to Moderately Severe Pain

Usual: 2 caps q4h prn
Max: 2 caps/4 hr; 5 doses (10 caps)/24 hrs

DOSING CONSIDERATIONS

Renal Impairment
Reduce dose

ADMINISTRATION

Oral route

HOW SUPPLIED

Cap: (APAP/Caffeine/Dihydrocodeine) 320.5mg/30mg/16mg

CONTRAINDICATIONS

Postoperative pain management in children who have undergone tonsillectomy and/or adenoidectomy; significant respiratory depression (in unmonitored settings or in the absence of resuscitative equipment); acute or severe bronchial asthma or hypercapnia; paralytic ileus.

WARNINGS/PRECAUTIONS

May produce orthostatic hypotension in ambulatory patients; caution in patients in circulatory shock. May aggravate convulsions in patients with convulsive disorders. Caution in elderly or debilitated patients or those with acute alcoholism, adrenocortical insufficiency (eg, Addison's disease), asthma, CNS depression or coma, chronic obstructive pulmonary disease, decreased respiratory reserve (eg, emphysema, severe obesity, cor pulmonale, kyphoscoliosis), delirium tremens, head injury, hypotension, increased intracranial pressure (ICP), myxedema or hypothyroidism, prostatic hypertrophy or urethral stricture, toxic psychosis, and hepatic/renal impairment. May obscure diagnosis or clinical course of acute abdominal conditions. Not recommended for use by women during and immediately before labor and delivery; may cause respiratory depression in the newborn. APAP: Increased risk of acute liver failure in patients with underlying liver disease. Rarely, may cause serious skin reactions (eg, acute generalized exanthematous pustulosis, Stevens-Johnson syndrome, toxic epidermal

necrolysis), which can be fatal; d/c at the 1st appearance of skin rash or any other sign of hypersensitivity. Hypersensitivity and anaphylaxis reported; avoid in patients with APAP allergy. Caution when using large doses in malnourished patients or those with history of chronic alcohol abuse; may be more susceptible to hepatic damage. Dihydrocodeine: Deaths reported in nursing infants exposed to high levels of morphine because their mothers were ultra-rapid metabolizers of codeine. Ultra-rapid metabolizers, due to specific CYP2D6 genotype (gene duplications denoted as *1/*1xN or *1/*2xN), may have life-threatening or fatal respiratory depression or experience signs of overdose (eg, extreme sleepiness, confusion, shallow breathing). Use lowest effective dose for the shortest period. May impair mental and/or physical abilities. May cause respiratory depression, most frequently in elderly or debilitated patients, usually after large initial doses in nontolerant patients; caution in patients with cor pulmonale, hypoxia hypercapnia, or respiratory depression; consider alternative nonopioid analgesics and administer opioids only under careful medical supervision. May obscure neurologic signs of increases in ICP in patients with head injuries. Respiratory depressant effects and secondary elevation of CSF pressure may be markedly exaggerated in the presence of head injury, intracranial lesions, or other causes of increased ICP. May cause hypotension in patients whose ability to maintain BP has been compromised by a depleted blood volume. May produce drug dependence and has potential for abuse. May cause spasms of the sphincter of Oddi; caution with biliary tract disease, including pancreatitis. Caffeine: May produce CNS and cardiovascular (CV) stimulation and GI irritation.

ADVERSE REACTIONS

Respiratory depression, acute liver failure, light-headedness, dizziness, drowsiness, headache, fatigue, sedation, sweating, N/V, constipation, pruritus, skin reactions, anxiety, excitement.

DRUG INTERACTIONS

Agonist/antagonist analgesics (eg, pentazocine, nalbuphine, butorphanol, buprenorphine) may reduce analgesic effect. Dihydrocodeine: Concomitant administration with other opioid analgesics, sedatives or hypnotics, muscle relaxants, general anesthetics, centrally acting antiemetics, phenothiazines or other tranquilizers, or alcohol may cause additive CNS depressant effects; when combination is contemplated, reduce dose of one or both agents. May cause respiratory depression with other agents that depress respiration. Concurrent use with phenothiazines or other agents that compromise vasomotor tone may cause hypotension. Caution with MAOIs; may cause CNS excitation and HTN. APAP: Chronic/excessive alcohol consumption may increase hepatotoxic risk. Risk may also be increased in patients receiving anticonvulsants that induce hepatic microsomal enzymes (eg, phenytoin, barbiturates, carbamazepine) or isoniazid. Chronic ingestion of large doses may slightly potentiate the effects of warfarin- and indandione-derivative anticoagulants. Severe hypothermia is possible with phenothiazines. Caffeine: May enhance the cardiac inotropic effects of β-adrenergic stimulating agents. Coadministration with disulfiram may decrease clearance. May increase the metabolism of phenobarbital and aspirin. Caffeine accumulation may occur when products or foods containing caffeine are consumed concomitantly with quinolones (eg, ciprofloxacin).

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

Dihydrocodeine: Semisynthetic narcotic analgesic; multiple actions, qualitatively similar to those of codeine. Principal action of therapeutic value is analgesia. APAP: Nonopiate, nonsalicylate analgesic and antipyretic. Caffeine: Analgesic adjuvant. Also a CNS and CV stimulant.

PHARMACOKINETICS

Distribution: Found in breast milk. **Metabolism:** Dihydrocodeine: Liver via CYP2D6; dihydromorphine (active metabolite).

ASSESSMENT

Assess for severity of pain, hypersensitivity to drug, significant respiratory depression, bronchial asthma, hypercapnia, paralytic ileus, hepatic/renal impairment, head injury, intracranial lesions, acute abdominal conditions, history of drug abuse or seizures, any other conditions where treatment is cautioned, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of hepatotoxicity, respiratory depression, hypotension, skin reactions, hypersensitivity, anaphylaxis, elevation in CSF pressure, drug abuse, tolerance, dependence, GI irritation, and other adverse reactions.

PATIENT COUNSELING

Instruct to d/c therapy and contact physician immediately if signs of allergy develop. Instruct to look for APAP on package labels and not to use >1 APAP-containing product. Instruct to seek medical attention immediately upon ingestion of >4000mg/day APAP, even if feeling well. Advise that drug may impair mental/physical abilities. Advise to report adverse experiences occurring during therapy. Advise not to adjust dose without consulting prescribing physician. Instruct not to combine medication with alcohol or other CNS depressants (sleep aids, tranquilizers) except by the orders of the prescribing physician, because additive effects may occur. Advise women of childbearing potential who become or are planning to become pregnant to consult their physician regarding the effects of analgesics and other drug use during pregnancy on themselves and their unborn child. Advise of the potential for abuse; instruct to protect drug from theft and never to give to anyone other than the individual for whom it was prescribed.

STORAGE

20-25°C (68-77°F). Dispense in a tight, light-resistant container with a child-resistant closure. Protect from moisture.

Back to top