Accolate (zafirlukast) - Drug Summary

Par Pharmaceutical, Inc.

Related Drug Information

Accolate (zafirlukast)

THERAPEUTIC CLASS

Leukotriene receptor antagonist

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Asthma

Prophylaxis and Chronic Treatment:
20mg bid

PEDIATRIC DOSAGE & INDICATIONS

Asthma

Prophylaxis and Chronic Treatment:
5-11 Years:
10mg bid

≥12 Years:
20mg bid

ADMINISTRATION

Oral route

Take at least 1 hr ac or 2 hrs pc

HOW SUPPLIED

Tab: 10mg, 20mg

CONTRAINDICATIONS

Hepatic impairment, including hepatic cirrhosis.

WARNINGS/PRECAUTIONS

Life-threatening hepatic failure and liver injury reported. D/C if liver dysfunction is suspected based upon signs/symptoms. Measure LFTs (particularly serum ALT) immediately and manage patient accordingly. Not for use in the reversal of bronchospasm in acute asthma attacks, including status asthmaticus. May continue therapy during acute exacerbations of asthma. Eosinophilic conditions (eg, systemic eosinophilia, eosinophilic pneumonia, or clinical features of vasculitis consistent with Churg-Strauss syndrome) may occur (rare); vasculitic rash, cardiac complications, and/or neuropathy may present. Neuropsychiatric events (eg, insomnia, depression) reported; carefully evaluate risks and benefits of continuing treatment if such events occur.

ADVERSE REACTIONS

Headache, infection, nausea.

DRUG INTERACTIONS

Coadministration with warfarin results in a clinically significant increase in PT; monitor PT closely and adjust anticoagulant dose accordingly when given with oral warfarin. Caution with drugs metabolized by CYP2C9 (eg, tolbutamide, phenytoin, carbamazepine). Decreased levels with erythromycin and liquid theophylline. May increase theophylline levels (rare). Increased levels with aspirin and fluconazole. Moderate and strong CYP2C9 inhibitors may increase exposure. Monitor when coadministered with drugs metabolized by CYP3A4 (eg, dihydropyridine calcium channel blockers, cyclosporine, cisapride).

PREGNANCY AND LACTATION

Category B, not for use in nursing.

MECHANISM OF ACTION

Leukotriene receptor antagonist; selective and competitive receptor antagonist of leukotriene D_4 and E_4, components of slow-reacting substance of anaphylaxis. Inhibits bronchoconstriction caused by several kinds of inhalational challenges.

PHARMACOKINETICS

Absorption: Rapid. (Adults) C_{max}=326ng/mL; T_{max}=2 hrs (median); AUC=1137ng•h/mL. C_{max}=601ng/mL (7-11 yrs of age); T_{max}=2.5 hrs; AUC=2027ng•h/mL. C_{max}=756ng/mL (5-6 yrs of age); T_{max}=2.1 hrs; AUC=2458ng•h/mL. **Distribution:** V_d=70L; plasma protein binding (>99%); found in breast milk. **Metabolism:** Liver (extensive), hydroxylation via CYP2C9. **Elimination:** Urine (10%), feces. (Adults) $T_{1/2}$=13.3 hrs.

ASSESSMENT

Assess for hypersensitivity to drug, hepatic impairment, hepatic cirrhosis, asthma status, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of eosinophilic conditions, vasculitic rash, worsening pulmonary symptoms, cardiac complications, neuropathy, neuropsychiatric events, and other adverse reactions. Monitor LFTs periodically. Closely monitor PT when given with oral warfarin.

PATIENT COUNSELING

Inform that hepatic dysfunction may occur; instruct to contact physician immediately if symptoms of hepatic dysfunction occur. Advise to take regularly as prescribed, even during symptom-free periods. Inform that it is not a bronchodilator and should not be used to treat acute episodes of asthma. Instruct not to decrease dose or stop taking any other antiasthma medications unless instructed by a physician. Instruct to notify physician if neuropsychiatric events occur. Instruct not to take the medication if breastfeeding.

STORAGE

20-25°C (68-77°F). Protect from light and moisture.

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