Hydroxyzine Hydrochloride Tablets (hydroxyzine hydrochloride) - Drug Summary

Teva Pharmaceuticals USA Inc

Related Drug Information ▼

Hydroxyzine HCl (hydroxyzine hydrochloride)

COMMON BRAND NAMES

Vistaril Injection (Discontinued), Hydroxyzine HCl

THERAPEUTIC CLASS

Piperazine antihistamine

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Pruritus

Management of pruritus due to allergic conditions (eg, chronic urticaria, atopic/contact dermatoses) and histamine-mediated pruritus

Syrup/Tab:
25mg tid or qid

Sedation

As premedication and following general anesthesia

Syrup/Tab:
50-100mg

Nausea/Vomiting

IM:
25-100mg; not for use in N/V of pregnancy

Surgery

As pre- and postoperative adjunctive medication to permit reduction in narcotic dosage, allay anxiety, and control emesis

IM:
25-100mg

Anxiety

Syrup/Tab:
Symptomatic relief of anxiety and tension associated w/ psychoneurosis and as an adjunct in organic disease states

50-100mg qid

IM:
Management of anxiety, tension, and psychomotor agitation in conditions of emotional stress. Useful in alleviating manifestations of anxiety/tension as in the preparation for dental procedures and in acute emotional

problems. Management of anxiety associated w/ organic disturbances and as adjunctive therapy in alcoholism and allergic conditions w/ strong emotional overlay (eg, asthma, chronic urticaria, pruritus). Treatment of acutely disturbed or hysterical patient and acute/chronic alcoholic w/ anxiety withdrawal symptoms or delirium tremens

50-100mg immediately, and q4-6h prn

Pregnancy

As pre- and postpartum adjunctive medication to permit reduction in narcotic dosage, allay anxiety, and control emesis

IM:
25-100mg

PEDIATRIC DOSAGE & INDICATIONS

Pruritus

Management of pruritus due to allergic conditions (eg, chronic urticaria, atopic/contact dermatoses) and histamine-mediated pruritus

Syrup/Tab:
<6 Years:
50mg/day in divided doses
>6 Years:
50-100mg/day in divided doses

Sedation

As premedication and following general anesthesia

Syrup/Tab:
0.6mg/kg

Nausea/Vomiting

Excluding N/V of pregnancy

IM:
0.5mg/lb

Surgery

As pre- and postoperative adjunctive medication to permit reduction in narcotic dosage, allay anxiety, and control emesis

IM:
0.5mg/lb

Anxiety

Symptomatic relief of anxiety and tension associated w/ psychoneurosis and as an adjunct in organic disease states

Syrup/Tab:
<6 Years:
50mg/day in divided doses
>6 Years:
50-100mg/day in divided doses

DOSING CONSIDERATIONS

Elderly
Start at lower end of dosing range

ADMINISTRATION

Oral/IM route

Adjust dose according to response.
When treatment is initiated by IM route, subsequent doses may be administered orally.

IM
May be administered w/o further dilution.
Inject well w/in the body of a relatively large muscle; preferred site in adults is the upper outer quadrant of the buttock or midlateral thigh and in children is the midlateral thigh.

HOW SUPPLIED

Inj: 25mg/mL [1mL], 50mg/mL [1mL, 2mL, 10mL]; **Syrup:** 10mg/5mL [118mL, 473mL]; **Tab:** 10mg, 25mg, 50mg

CONTRAINDICATIONS

Prolonged QT interval, known hypersensitivity to hydroxyzine HCl, early pregnancy. **Inj:** SQ, intra-arterial, or IV administration. **Syrup/Tab:** Known hypersensitivity to cetirizine or levocetirizine.

WARNINGS/PRECAUTIONS

Patients may be started on IM therapy when indicated and should be maintained on oral therapy whenever this route is practicable. QT prolongation and torsades de pointes reported; caution in patients w/ risk factors for QT prolongation, congenital long QT syndrome, a family history of long QT syndrome, other conditions that predispose to QT prolongation, ventricular arrhythmia, recent MI, uncompensated heart failure, and bradyarrhythmias. Drowsiness may occur. May impair mental/physical abilities. Caution in elderly. **Inj:** Should not be used as sole treatment of psychosis or for clearly demonstrated cases of depression. Inadvertent SQ inj may result in significant tissue damage. IM inj may result in severe inj-site reactions requiring surgical intervention. Inj into the deltoid area should be used only if well developed (eg, certain adults and older children), and then only w/ caution to avoid radial nerve injury. In infants and small children, inj into the periphery of the upper outer quadrant of the gluteal region should be used only when necessary, in order to minimize the possibility of damage to the sciatic nerve. IM inj in children should not be made into the lower and mid-third of the upper arm.

ADVERSE REACTIONS

Dry mouth, drowsiness, involuntary motor activity.

DRUG INTERACTIONS

May potentiate CNS depressants (eg, narcotics, non-narcotic analgesics and barbiturates, alcohol); reduce dose of CNS depressants when administered concomitantly. Modify use of meperidine and barbiturates, on an individual basis, when used in preanesthetic adjunctive therapy. Caution during the concomitant use of drugs known to prolong the QT interval (eg, quinidine, amiodarone, sotalol, ziprasidone, clozapine, quetiapine, chlorpromazine, fluoxetine, azithromycin, erythromycin, moxifloxacin, pentamidine, methadone, ondansetron, droperidol). **Inj:** Cardiac arrests and death reported when combined w/ other CNS depressants. Administration of meperidine may result in severe hypotension in the postoperative patient or any individual whose ability to maintain BP has been compromised by a depleted blood volume. Use meperidine w/ great caution and in reduced dosage in patients who are receiving other pre- and/or postoperative medications and in whom there is a risk of respiratory depression, hypotension, and profound sedation or coma occurring.

PREGNANCY AND LACTATION

Pregnancy: Contraindicated in early pregnancy.
Lactation: Syrup/Tab: Not for use in nursing; **Inj:** Safety not known in nursing.

MECHANISM OF ACTION

Piperazine antihistamine; believed to suppress activity in certain key regions of the subcortical area of the CNS and shown to have primary skeletal muscle relaxation and antihistaminic effects. (PO) Shown to have bronchodilator activity and analgesic effects. (Inj) Shown to have antispasmodic and antiemetic effects.

PHARMACOKINETICS

Absorption: (PO) Rapid.

ASSESSMENT

Assess for hypersensitivity to drug, QT prolongation, risk factors for QT prolongation, pregnancy/nursing status, and for possible drug interactions. **Syrup/Tab:** Assess for hypersensitivity to cetirizine or levocetirizine.

MONITORING

Monitor for hypersensitivity reactions, QT prolongation, torsades de pointes, drowsiness, and other adverse reactions. Periodically reassess the usefulness of therapy.

PATIENT COUNSELING

Inform about risks/benefits of therapy. Inform that drowsiness may occur; instruct to use caution when driving or operating heavy machinery. Instruct to notify physician if pregnant, nursing, or taking any other concomitant therapy.

STORAGE

20-25°C (68-77°F). **Inj:** Excursions permitted to 15-30°C (59-86°F). **Syrup:** Protect from freezing. **Inj/Syrup:** Protect from light.

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