Amitriptyline Hydrochloride (amitriptyline hydrochloride) - Drug Summary

Mylan Pharmaceuticals Inc.

Related Drug Information

Amitriptyline (amitriptyline hydrochloride)

BOXED WARNING

Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder and other psychiatric disorders. Monitor and observe closely for clinical worsening, suicidality, or unusual changes in behavior in patients who are started on antidepressant therapy. Not approved for use in pediatric patients.

COMMON BRAND NAMES

Elavil (Discontinued), Amitriptyline

THERAPEUTIC CLASS

Tricyclic antidepressant (TCA)

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Depression

Outpatients:
Initial (Divided Dose): 75mg/day in divided doses
Titrate: May increase to 150mg/day; increases are made preferably in the late afternoon and/or hs doses

Initial (Single Dose): 50-100mg at hs
Titrate: May increase by 25mg or 50mg in the hs dose, to a total of 150mg/day

Hospitalized Patients:
Initial: 100mg/day
Titrate: May increase gradually to 200mg/day; some patients as much as 300mg/day

Maint: 50-100mg/day (40mg/day is sufficient in some patients); total daily dose may be given in a single dose, preferably at hs. Continue ≥3 months

PEDIATRIC DOSAGE & INDICATIONS

Depression

≥12 Years:
10mg tid w/ 20mg at hs

DOSING CONSIDERATIONS

Elderly
10mg tid w/ 20mg at hs

ADMINISTRATION

Oral route

HOW SUPPLIED

Tab: 10mg, 25mg, 50mg, 75mg, 100mg, 150mg

CONTRAINDICATIONS

Use of an MAOI concomitantly. Treatment w/in 14 days of discontinuing an MAOI. Coadministration w/ cisapride. During the acute recovery phase following myocardial infarction (MI).

WARNINGS/PRECAUTIONS

Not approved for the treatment of bipolar depression. May precipitate a mixed/manic episode in patients at risk for bipolar disorder; screen for risk for bipolar disorder prior to initiating treatment. Caution w/ history of seizures, history of urinary retention, angle-closure glaucoma, or increased IOP. Caution w/ cardiovascular disorders (CVD), hyperthyroidism, liver dysfunction, and in elderly. Pupillary dilation that occurs following therapy may trigger an angle-closure attack in a patient w/ anatomically narrow angles who does not have a patent iridectomy. Dose may be reduced or a major tranquilizer (eg, perphenazine) may be administered concurrently if schizophrenic patients develop increased symptoms of psychosis (patients w/ paranoid symptomatology may have an exaggeration of such symptoms), or if depressed patients, particularly those w/ known manic-depressive illness, experience a shift to mania or hypomania. Hazards may be increased w/ electroshock therapy. D/C several days before elective surgery. May alter blood glucose levels.

ADVERSE REACTIONS

MI, stroke, coma, seizures, paralytic ileus, hyperpyrexia, skin rash, urticaria, bone marrow depression, N/V, epigastric distress, increased/decreased libido, alopecia, edema.

DRUG INTERACTIONS

See Contraindications. May block antihypertensive action of guanethidine or similarly acting compounds. Caution in patients receiving thyroid medication. May enhance the response to alcohol and the effects of barbiturates and other CNS depressants. Delirium reported w/ disulfiram. Drugs that inhibit CYP2D6 (eg, quinidine, cimetidine, many CYP2D6 substrates [other antidepressants, phenothiazines, propafenone, flecainide]) may increase plasma concentrations; may require lower doses for either TCA or the other drug, and monitoring of TCA plasma levels. Caution w/ SSRI coadministration and when switching between TCAs and SSRIs (eg, fluoxetine, sertraline, paroxetine); sufficient time must elapse before starting therapy when switching from fluoxetine (at least 5 weeks may be necessary). Close supervision and careful dose adjustment is required when given w/ anticholinergic agents or sympathomimetic drugs, including epinephrine combined w/ local anesthetics. Hyperpyrexia reported w/ anticholinergics or neuroleptics, particularly during hot weather. Paralytic ileus may occur w/ anticholinergic-type drugs. Caution w/ large doses of ethchlorvynol; transient delirium reported.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

TCA; has not been established. Inhibits the membrane pump mechanism responsible for uptake of norepinephrine and serotonin in adrenergic and serotonergic neurons.

PHARMACOKINETICS

Absorption: Rapid. **Distribution:** Found in breast milk; crosses the placenta. **Metabolism:** N-demethylation and bridge hydroxylation. **Elimination:** Urine (unchanged).

ASSESSMENT

Assess for acute recovery phase following MI, hypersensitivity to drug, risk for bipolar disorder, history of seizures or urinary retention, susceptibility to angle-closure glaucoma, increased IOP, CVD, hyperthyroidism, liver dysfunction, schizophrenia, paranoid symptomatology, manic-depressive illness, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of clinical worsening, suicidality, unusual changes in behavior, angle-closure glaucoma, increased psychosis symptoms, exaggeration of paranoid symptoms, hypomanic/manic episodes, changes in blood glucose levels, and other adverse reactions.

PATIENT COUNSELING

Inform about benefits, risks, and appropriate use of therapy. Advise that drug may impair mental/physical abilities required for the performance of hazardous tasks (eg, operating machinery, driving). Caution about the risk of angle-closure glaucoma. Advise to monitor for unusual changes in behavior, worsening of depression, and suicidal ideation on a day-to-day basis, and to report such symptoms to physician.

STORAGE

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

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