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ALDOMET Tablets/Injections

Merck Sharp & Dhome

methyldopa

Presentation

Aldomet 250 mg. Tablets are available in packs of 30 and 100 tablets.

Aldomet 500 mg. Tablets are available in packs of 30 and 100 tablets.

Composition

Tablets 125 mg, 250 mg and 500 mg methyldopa anh.

Properties

Aldomet is an effective antihypertensive agent that reduces both supine and standing blood pressure.

Indication

Hypertension.

Dosage and administration

The 125 mg tablet is valuable when small increments of methyldopa are required for adjustment of antihypertensive response. The 500 mg tablet is intended for use in patients requiring two 250 mg tablets at any given dose.

Adults

The usual starting dosage of Aldomet is 250 mg two or three times a day in the first 48 hours. The daily dosage then may be increased or decreased, preferably at intervals of not less than two days, until an adequate response is achieved. The maximum recommended daily dosage is 3 g. Many patients experience sedation for two or three days when therapy with Aldomet is started or when the dose is increased. When increasing the dosage, therefore, it may be desirable to increase the evening dose first.

General considerations

Withdrawal of Aldomet is followed by return of hypertension usually within 48 hours. This is not complicated by an overshoot of blood pressure.

When methyldopa is given to patients on other antihypertensives, the dose of these agents may need to be adjusted to effect a smooth transition.

Children

Initial dosage is based on 10 mg/kg of body weight daily in two to four doses. The daily dosage then is increased or decreased until an adequate response is achieved. The maximum dosage is 65 mg/kg or 3.0 g daily whichever is less.

Contraindications

Active hepatic disease, such as acute hepatitis and active cirrhosis; hypersensitivity to any of the components of this product (including hepatic disorders associated with previous methyldopa therapy).

Warnings and precautions

Acquired hemolytic anemia has occurred rarely in association with methyldopa therapy. Evidence of hemolytic anemia is an indication for discontinuation of the drug. Discontinuation of methyldopa alone or the initiation of adrenocortical steroids usually results in a prompt remission of anemia. Rarely, however, fatalities have occurred.

Rarely, a reversible reduction of the white blood cell count with a primary effect on the granulocytes has been seen. The granulocyte count returned promptly to normal on discontinuance of the drug. Reversible thrombocytopenia has occurred rarely.

Occasionally, fever occurred within the first three weeks of administration of methyldopa. In some cases this fever has been associated with eosinophilia or abnormalities in one or more liver function tests. Jaundice, with or without fever, may occur also, with onset usually the first two or three months of therapy. A determination of hepatic function and a white cell and differential blood count should be done at intervals during the first 6-12 weeks of therapy, or whenever an unexplained fever may occur. If fever, abnormalities in liver function tests, or jaundice appear, therapy with methyldopa should be stopped.

Interactions

When methyldopa and lithium are given concomi-

tantly the patient should be monitored carefully for symptoms of lithium toxicity.

When methyldopa is used in combination with other antihypertensive drugs, potentiation of antihypertensive action may occur.

Patient may require reduced doses of anesthetics when on Aldomet. If hypotension does occur during anesthesia, it usually can be controlled by vasopressors. The adrenergic receptors remain sensitive during treatment with methyldopa.

Use in pregnancy and during lactation

Methyldopa has been used under close medical and obstetric supervision for the treatment of hypertension during pregnancy. There was no clinical evidence that methyldopa caused fetal abnormalities or affected the neonate. To date, there has been no evidence of harmfulness in animal trials. Methyldopa does cross the placental barriers and appears in cord blood and breast milk. If use of Aldomet is deemed essential, the patient should stop nursing.

Side effects

Sedation, usually transient, may occur during the initial period of therapy or whenever the dose is increased. Headache, asthenia, or weakness may be noted as early and transient symptoms.

The following reactions have been reported.

Central nervous system: sedation (usually transient), headache, asthenia or weakness, paresthesias, parkinsonism, Bell's palsy, involuntary choreoathetotic movements. Psychic disturbances including nightmares, impaired mental acuity and reversible mild psychoses or depression. Dizziness, lightheadedness, and symptoms of cerebrovascular insufficiency (may be due to lowering of blood pressure).

Cardiovascular: bradycardia, prolonged carotid sinus hypersensitivity, aggravation of angina pectoris. Orthostatic hypotension (decrease daily dosage). Edema (and weight gain) usually relieved by use of diuretic. (Discontinue methyldopa if edema progresses or signs of heart failure appear).

Gastrointestinal: nausea, vomiting, distension, constipation, flatus, diarrhea, colitis, mild dryness of mouth, sore or 'black' tongue, pancreatitis, sialoadenitis.

Hepatic: liver disorders including hepatitis, jaundice, abnormal liver function tests.

Hematologic: positive Coombs tests, hemolytic anemia, bone marrow depression, leukopenia, granulocytopenia, thrombocytopenia. Positive tests for antinuclear antibody, LE cells, and rheumatoid factor.

Allergic: drug-related fever and abnormal liver function tests with jaundice (see Warnings and precautions), lupus-like syndrome with myocarditis and pericarditis.

Dermatologic: rash as in eczema or lichenoid eruption; toxic epidermal necrolysis.

Other: nasal stuffiness, rise in BUN, breast enlargement, gynecomastia, lactation, hypoprolactinemia, amenorrhea, impotence, decreased libido, mild arthralgia with or without joint swelling, myalgia.

Overdosage

Contact your physician immediately in case of overdosage.

Storage

As indicated on the outer pack of the product.

Keep all medicines safely away from children.