

Hydralazine hydrochloride

Introduction: An antihypertensive, available as 10-, 25-, 50-, and 100-mg tablets for oral administration.

Mechanism of action: The mechanism of action of hydralazine is not well known. It interferes with the action the second messenger inositol triphosphate, limiting calcium release from the sarcoplasmic reticulum of smooth muscle. This results in an arterial and arteriolar relaxation.

Dosage: Initiate therapy in gradually increasing dosages; adjust according to individual response. Start with 10 mg four times daily for the first 2-4 days, increase to 25 mg four times daily for the balance of the first week. For the second and subsequent weeks, increase dosage to 50 mg four times daily. For maintenance, adjust dosage to the lowest effective levels. In a few resistant patients, up to 300 mg of Hydralazine daily may be required for a significant antihypertensive effect. In such cases, a lower dosage of Hydralazine combined with a thiazide and/or reserpine or a beta blocker may be considered. However, when combining therapy, individual titration is essential to ensure the lowest possible therapeutic dose of each drug.

Side effects: Adverse reactions with Hydralazine are usually reversible when dosage is reduced. However, in some cases it may be necessary to discontinue the drug. The following adverse reactions have been observed, but there has not been enough systematic collection of data to support an estimate of their frequency.

Common: Headache, anorexia, nausea, vomiting, diarrhea, palpitations, tachycardia, angina pectoris.

Less Frequent: Digestive: constipation, paralytic ileus.

Cardiovascular: hypotension, paradoxical pressor response, edema.

Respiratory: dyspnea.

Neurologic: peripheral neuritis evidenced by paresthesia, numbness, and tingling, dizziness; tremors; muscle cramps; psychotic reactions characterized by depression, disorientation, or anxiety.

Genitourinary: difficulty in urination.

Hematologic: blood dyscrasias, consisting of reduction in hemoglobin and red cell count, leukopenia, agranulocytosis, purpura, lymphadenopathy; splenomegaly.

Hypersensitive Reactions: rash, urticaria, pruritus, fever, chills, arthralgia, eosinophilia, and, rarely, hepatitis.

Other: nasal congestion, flushing, lacrimation, conjunctivitis.

Precautions:

General: Myocardial stimulation produced by Hydralazine can cause anginal attacks and ECG changes of myocardial ischemia. The drug has been implicated in the production of myocardial infarction. It must, therefore, be used with caution

in patients with suspected coronary artery disease. The drug may reduce the pressor responses to epinephrine. Postural hypotension may result from Hydralazine but is less common than with ganglionic blocking agents. It should be used with caution in patients with cerebral vascular accidents. In hypertensive patients with normal kidneys who are treated with Hydralazine, there is evidence of increased renal blood flow and a maintenance of glomerular filtration rate. In some instances where control values were below normal, improved renal function has been noted after administration of Hydralazine. However, as with any antihypertensive agent, Hydralazine should be used with caution in patients with advanced renal damage.

Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. Although clinical experience does not include any positive evidence of adverse effects on the human fetus, hydralazine should be used during pregnancy only if the expected benefit justifies the potential risk to the fetus.

Nursing Mothers: Hydralazine has been shown to be excreted in breast milk.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established in controlled clinical trials, although there is experience with the use of Hydralazine in these patients. The usual recommended oral starting dosage is 0.75 mg/kg of body weight daily in four divided doses. Dosage may be increased gradually over the next 3-4 weeks to a maximum of 7.5 mg/kg or 200 mg daily.

Contraindications: Hypersensitivity to hydralazine; coronary artery disease; mitral valvular rheumatic heart disease.

How supplied: Customized as per request.