HemiClor®
chlorthalidone
12.5 mg

IMPORTANT SAFETY INFORMATION

INDICATION

HEMICLOR (12.5 mg, chlorthalidone) is a thiazide-like diuretic indicated for the treatment of hypertension in adults, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. These benefits have been seen in controlled trials of antihypertensive drugs from a wide variety of pharmacologic classes including the class to which HemiClor principally belongs.

IMPORTANT SAFETY INFORMATION

Contraindications:
HemiClor is contraindicated in patients with anuria or known hypersensitivity to chlorthalidone or sulfonamide-derived drugs.

WARNINGS AND PRECAUTIONS

Acute Kidney Injury: Diuretics can cause hypovolemia which may precipitate acute kidney injury. Patients with chronic kidney disease, heart failure, or volume depletion may be at particular risk. Consider withholding or discontinuing therapy in patients who develop clinically significant decreases in kidney function.

Electrolyte Abnormalities: Chlorthalidone can cause hypokalemia, hyponatremia, hypochloremic alkalosis, and hypomagnesemia. Hypomagnesemia can result in hypokalemia that is difficult to treat despite potassium repletion. Hypokalemia is dose dependent. Monitor and correct serum electrolytes prior to use and monitor periodically.

Metabolic Disturbances: Chlorthalidone may increase blood sugar levels**,** affect diabetes control, and cause changes in the need for diabetes medication. It may also cause a rise in serum levels of cholesterol and triglycerides. Monitoring blood sugar and lipid levels is recommended.

Chlorthalidone may increase serum uric acid levels due to reduced clearance of uric acid and may cause or exacerbate hyperuricemia and precipitate gout in susceptible patients. Increases in serum uric acid are dose related.

Chlorthalidone decreases urinary calcium excretion and may cause elevations of serum calcium. Calcium levels should be monitored.

Systemic Lupus Erythematosus: Exacerbation or activation of lupus erythematosus has been reported with thiazide diuretics which are structurally related to chlorthalidone. However, systemic lupus erythematosus has not been reported following chlorthalidone administration.

Continued on next page

Adverse Reactions: In addition to the adverse reactions identified above associated with Acute Kidney Injury, Electrolyte Abnormalities, and Metabolic Disturbances, the following adverse reactions have been observed with chlorthalidone, but there is not enough systematic collection of data to support an estimate of their frequency:

- **Gastrointestinal System Reactions:** anorexia, gastric irritation, nausea, vomiting, cramping, diarrhea, constipation, jaundice (intrahepatic cholestatic jaundice), pancreatitis;
- **Central Nervous System Reactions:** dizziness, paresthesias, headache;
- **Hematologic Reactions:** leukopenia, agranulocytosis, thrombocytopenia, aplastic anemia;
- **Dermatologic-Hypersensitivity Reactions:** purpura, photosensitivity, rash, urticaria, necrotizing angiitis (vasculitis) (cutaneous vasculitis), Lyell's syndrome (toxic epidermal necrolysis);
- **Cardiovascular Reaction:** Orthostatic hypotension; and
- **Other Adverse Reactions:** muscle spasm, weakness, restlessness, impotence, xanthopsia.

Drug Interactions: With chlorthalidone, insulin requirements in diabetic patients may be increased, decreased or unchanged. Higher dosage of oral hypoglycemic agents may be required. Chlorthalidone may increase the responsiveness to tubocurarine and may decrease arterial responsiveness to norepinephrine. This diminution is not sufficient to preclude effectiveness of the pressor agent for therapeutic use. Lithium renal clearance is reduced by chlorthalidone, increasing the risk of lithium toxicity. Monitor serum lithium levels during concomitant use.

Dosing Information: Therapy should be initiated with the lowest possible dose. The recommended adult initial dose of HEMICLOR is 12.5 mg or 25 mg given orally with food once daily. Double the dose every 2-4 weeks as needed based on individual patient response, up to a maximum of 100mg once daily. Dosages above 100mg daily usually do not increase effectiveness.

These are not all the possible side effects of chlorthalidone. Please see the full Prescribing Information, available at www.prmpharma.com,