Chlorothiazide Sodium for Injection is indicated as adjunctive therapy in edema associated with congestive heart failure, hepatic cirrhosis, and corticosteroid and estrogen therapy.

Useful in edema due to various forms of renal dysfunction such as nephrotic syndrome, acute glomerulonephritis, and chronic renal failure.

Chlorothiazide Sodium for Injection is contraindicated in anuria and for patients with hypersensitivity to any component of this product or to other sulfonamide-derived drugs.

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**Chlorothiazide Sodium for Injection**

- **ACTIVE:** Chlorothiazide Sodium equivalent to 500 mg Chlorothiazide;
- **PRESERVATIVE:** None;
- **INACTIVES:** 250 mg Mannitol and Sodium Hydroxide to adjust pH;
- **STORAGE:** Store at 20° to 25°C (68° to 77°F)

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**NOT FOR PRESCRIBING PURPOSES. PLEASE REFER TO PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION.**
Chlorothiazide Sodium for Injection

PRECAUTIONS

DESCRIPTION
Chlorothiazide Sodium for Injection is a diuretic and antihypertensive. It is 6-chloro-2-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide sodium salt. The molecular weight is 295.72, and its empirical formula is C_{6}H_{7}ClNa_{2}O_{5}S. Its structural formula is:

![Structural formula of Chlorothiazide Sodium](image)

It is a white, or practically white, crystalline powder with a molecular weight of 295.72, which is very slightly soluble in water, but readily soluble in dilute aqueous sodium hydroxide. It is soluble in urine to the extent of about 150 mEq per 100 ml at pH 7.

CHLOROTHIAZIDE PHARMACOLOGY

The mechanism of the antihypertensive action of thiazides is unknown. Chlorothiazide does not usually affect normal blood pressure. Chlorothiazide affects the distal renal tubular mechanism of electrolyte reabsorption. At maximal therapeutic dosage all thiazides are equally effective in their diuretic efficacy.

Chlorothiazide increases excretion of sodium and chloride in approximately equivalent amounts. The urine electrolyte content may be accompanied by some loss of potassium and bicarbonate. After oral use diuretic begins within 3 hours, peaks in about 4 hours and lasts about 12 to 18 hours. Follow the intravenous injection of chlorothiazide, onset of the diuretic action occurs in 15 minutes and maximal diuresis in 30 minutes.

PHARMACOKINETICS AND METABOLISM
Chlorothiazide is not metabolized but is eliminated rapidly by the kidney; 96% of an intravenous dose is excreted unchanged in the urine within 24 hours. The plasma half-life of chlorothiazide is about 24-48 hours. Chlorothiazide crosses the placental but not the blood-brain barrier and is excreted in breast milk.

INDICATIONS AND USAGE
Chlorothiazide Sodium for Injection is indicated for administration in edema associated with congestive heart failure, hepatic cirrhosis, and congestive and edematous states of chronic renal failure.

Use in Pregnancy
Routine use of diuretics during normal pregnancy is inappropriate and exposes both mother and fetus to unnecessary hazard. Diuretics do not prevent development of toxemia of pregnancy and there is no satisfactory evidence that they are beneficial in the treatment of edema due to pathologic causes or from the physiologic edema of pregnancy.

Edema due to normal pregnancy is diagnosed in pregnancy when edema is due to pathologic causes, just as they are in the absence of pregnancy (see PRECAUTIONS, Pregnancy). Dependent edema develops in the normal pregnant state in the last trimester, is properly treated through elevation of the lower extremities and use of support hose. Use of diuretics in pregnancy may be associated with edema, rarely general edema. If such edema causes discomfort, increased recency will often provide relief. Rarely this edema may cause extreme discomfort which is not relieved by the above measures. In such cases, a short course of diuretic therapy may provide relief and be appropriate.

CONTRAINDICATIONS
Hypersensitivity to any component of this product or to other sulfonamide-derived drugs.

WARNINGS
Intravenous use in infants and children has been limited and is not generally recommended. Use with caution in severe renal disease. In patients with renal disease, thiazides may precipitate acute intercurrent effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function and in those having concurrent illness, which may alter fluid and electrolyte balance may precipitate hepatic coma. Thiazides may add to or potentiate the action of other antihypertensive drugs.

Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma. The possibility of exacerbation or activation of systemic lupus erythematosus has been reported. Lithium generally should not be given with diuretics (see PRECAUTIONS, Drug Interactions).

PRECAUTIONS

General
All patients receiving diuretic therapy should be observed for evidence of fluid or electrolyte imbalance: namely, hypernatremia, hyperchloremic alkalai-