CHLOROTHIAZIDE SODIUM FOR INJECTION, USP
Rx-Only
FOR THE PREPARATION OF INTRAVENOUS SOLUTIONS

DESCRIPTION
Chlorothiazide injection, USP is a diuretic and antihypertensive. It is a 6-chloro-2H-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide. Its empirical formula is C9H6ClN3O5S2 and its molecular weight is 317.71. Its structural formula is:

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\text{CIN,0,S}
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It is a white, or practically white, crystalline powder with a molecular weight of 302.75, which is very slightly soluble in water, but readily soluble in dilute aqueous solutions of hydrochloric acid. It is soluble in water to the extent of about 150 mg per ml.

INDICATIONS AND USAGE
Chlorothiazide sodium for injection, USP has also been found useful in edema of various forms such as congestive heart failure, hepatic cirrhosis, and nephrotic syndrome.

Chlorothiazide sodium for injection, USP, when added to the diet of patients with impaired renal function, may be of value in the medical management of edema associated with the following conditions:

- Edema associated with congestive heart failure.
- Edema associated with hepatic cirrhosis.
- Edema associated with nephrotic syndrome.
- Edema associated with conditions that result in renal edema, such as those associated with severe liver disease.

Chlorothiazide sodium for injection, USP is a potent diuretic and as such is potentially harmful to the fetus or the mother in the absence of cardiovascular disease. However, it may be associated with edema, rarely generalized edema. If such effects should occur, increased heart and respiratory rates, and a decrease in the hematocrit may be noted. In these instances, a short course of diuretic therapy may provide relief and be appropriate.

CLINICAL PHARMACOLOGY
Thiazides may decrease urinary calcium excretion. Thiazides may cause intermittent and slight elevation of serum calcium in the absence of known disorders of calcium metabolism. Marked hypercalcemia may be evidence of hidden hyperparathyroidism. Thiazides should be discontinued before carrying out tests of parathyroid function.

Thiazides have been shown to increase the urinary excretion of magnesium; this may result in hypomagnesemia.

The antihypertensive effects of the drug may be enhanced in the postsympathectomy patient.

The possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

Thiazides may add to or potentiate the action of other antihypertensive drugs.

Thiazides should be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma.

Thiazides increase uric acid excretion and therefore may precipitate gouty attacks in patients with gout.

The possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

Thiazides may cause or potentiate the action of other antihypertensive drugs. Diuretics do not prevent development of toxemia of pregnancy and there is no satisfactory evidence that they are useful in the treatment of toxemia.

Thiazides may increase the uricosuric effect of certain xanthine derivate drugs, such as theophylline.

Increases in cholesterol and triglyceride levels may be associated with thiazide diuretic therapy.

Hypouricemia may be observed in certain patients receiving thiazides. Although any chloride deficit is generally mild and usually does not require specific treatment except under extraordinary circumstances (as in liver disease or renal disease), chloride replacement may be required in the treatment of metabolic alkalosis.

The antihypertensive effects of the drug may be reversed by sodium administration.

Hypersensitivity to any component of this product, or to other sulfa-derived drugs, may occur.

The antihypertensive effects of the drug may be potentiated by the following drugs: Potassium-sparing diuretics or potassium supplements such as foods with a high potassium content.

Drug Interactions
Hypokalemia may develop especially with brisk diuresis, when severe cirrhosis is present or after prolonged therapy.

Indications: Oral dosage forms are available in pellets, or as capsules, tablets, or in injectable form.

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Chlorothiazide Sodium For Injection, USP is a sterile lyophilized white powder and is supplied in a vial containing:

- Chlorothiazide sodium equivalent to Chlorothiazide 500 mg.

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Patients with a history of allergy to sulfonamides may be considered Cross-reactive sensitivities may exist among those sulfonamide-containing drugs that differ in molecular weight and structure.

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