DISCLAIMER

All labeling reflected on this website is for informational and promotional purposes only. It is not intended to be used by healthcare professionals or patients for the purpose of prescribing or administering these products. Questions regarding the current content of product labeling should be directed to Akorn's Customer Service department at 800.932.5676.
**Chlorothiazide Sodium for Injection, USP**

FOR THE PREPARATION OF INTRAVENOUS SOLUTION

**DESCRIPTION**

Chlorothiazide Sodium for Injection, USP is a diuretic and antihypertensive. It is 6-chloro-2H-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide monosodium salt and its molecular weight is 317.71. Its empirical formula is C$_7$H$_5$ClN$_3$NaO$_4$S$_2$ and its structural formula is:

![Structural formula of Chlorothiazide](image)

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

Inactive ingredients:

- Mannitol .............................................................................................................................. 250 mg
- Sodium hydroxide to adjust pH.

Chlorothiazide is a diuretic and antihypertensive. It is 6-chloro-2H-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide. Its empirical formula is C$_7$H$_6$ClN$_3$O$_4$S$_2$ and its structural formula is:

![Structural formula of Chlorothiazide](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 mg per 100 mL at pH 7.

**CLINICAL PHARMACOLOGY**

The mechanism of the antihypertensive effect 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 approximately equal in their diuretic efficacy.

Chlorothiazide increases excretion of sodium and chloride in approximately equivalent amounts. Natriuresis may be accompanied by some loss of potassium and bicarbonate.

After oral use diuresis begins within 2 hours, peaks in about 4 hours and lasts about 6 to 12 hours. Following intravenous use of Chlorothiazide Sodium, onset of the diuretic action occurs in 15 minutes and the maximal action in 30 minutes.

**Pharmacokinetics and Metabolism**

Chlorothiazide is not metabolized but is eliminated rapidly by the kidney. 96 percent of an intravenous dose is excreted unchanged in the urine within 23 hours. The plasma half-life of chlorothiazide is 45 to 120 minutes. 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 as adjunctive therapy in edema associated with congestive heart failure, hepatic cirrhosis, and corticosteroid and estrogen therapy.

Chlorothiazide Sodium for Injection has also been found useful in edema due to various forms of renal dysfunction such as nephrotic syndrome, acute glomerulonephritis, and chronic renal failure.

**Use in Pregnancy**

Routine use of diuretics during normal pregnancy is inappropriate and exposes mother and fetus to unnecessary hazard. Diuretics do not prevent development of toxemia of pregnancy and there is no satisfactory evidence that they are useful in the treatment of toxemia.
Edema during pregnancy may arise from pathologic causes or from the physiologic and mechanical conse-
quences of pregnancy. Pregnant women may develop edema due to decreased plasma volume, just as they are in the absence of pregnancy (see PRECAUTIONS, Pregnancy). Dependent edema in pregnancy, resulting from restriction of venous return by the gravid uterus, is properly treated through positioning of the lower extremities and use of support stockings. Use of diuretics to lower intravascular volume in this instance is illogical and unnecessary. During normal pregnancy there is hypercalcemia which is not harm-
ful to the fetus or the mother in the absence of cardiovascular disease. However, it may be associated with edema, rarely generalized edema. If such edema causes discomfort, increased reoccurrence will often provide relief. This edema may cause extreme discomfort which is not relieved by rest. In these instances, a short course of diuretic therapy may provide relief and be appropriate.

CONTRAINDICATIONS

Anuria

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 azotemia. Cumulative effects of the drug may develop in patients with-insufficient renal function.

Thiazides should be used with caution in patients with impaired hepatic function or progressive liver dis-
ease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma. Thi-
azides may add or potentiate the action of other antihypertensive drugs.

Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma.

Thiazides have been shown to increase the urinary excretion of magnesium; this may result in hypomag-
esemia. Whenever adverse reactions are moderate or severe, thiazide dosage should be reduced or therapy with-
drawn. To report SUSPECTED ADVERSE REACTIONS, contact Akorn, Inc. at 1-800-922-5676 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE

The most common signs and symptoms observed are those caused by electrolyte depletion (hyponatremia, hy-
pokalemia, hypochloremia, hypernatremia) and dehydration resulting from excessive diuresis. If diabetics has also been administered, hyponatremia may accentuate cardiac arrhythmias. In the event of overdose, symptomatic and supportive measures should be employed. Correct dehydra-
tion, electrolyte imbalance, hepatic coma and hypotension by established procedures. If required, give oxygen or arterial pressure for respiratory support. The degree to which chlorothiazide sodium is removed by hemodialysis has not been established. The intravenous dose of chlorothiazide in the mouse is 1.1 g/kg.

DOSE AND ADMINISTRATION

Chlorothiazide Sodium for injection should be reserved for patients unable to take oral medication or for emergency situations. Therapy should be individualized according to patient response. Use the smallest dosage necessary to achieve the required response. Intravenous use in infants and children has been limited and is not generally recommended.

When medication can be taken orally, therapy with Chlorothiazide tablets or oral suspension may be substi-
tuted for intravenous therapy, using the same dosage schedule as for the parenteral route.

Hyperglycemia may occur with thiazide diuretics. Thus latent diabetes mellitus may become manifest dur-
ing therapy. Electrolyte imbalance, hepatic coma and hypotension by established procedures. If required, give oxygen or arterial pressure for respiratory support. The degree to which chlorothiazide sodium is removed by hemodialysis has not been established. The intravenous dose of chlorothiazide in the mouse is 1.1 g/kg.

Chlorothiazide Sodium for injection may be given by slow direct intravenous injection or by intravenous infusion.

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 azotemia. Cumulative effects of the drug may develop in patients with-insufficient renal function.

Thiazides should be used with caution in patients with impaired hepatic function or progressive liver dis-
ease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma. Thi-
azides may add or potentiate the action of other antihypertensive drugs.

Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma.

Thiazides have been shown to increase the urinary excretion of magnesium; this may result in hypomag-
esemia. Whenever adverse reactions are moderate or severe, thiazide dosage should be reduced or therapy with-
drawn. To report SUSPECTED ADVERSE REACTIONS, contact Akorn, Inc. at 1-800-922-5676 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE

The most common signs and symptoms observed are those caused by electrolyte depletion (hyponatremia, hy-
pokalemia, hypochloremia, hypernatremia) and dehydration resulting from excessive diuresis. If diabetics has also been administered, hyponatremia may accentuate cardiac arrhythmias. In the event of overdose, symptomatic and supportive measures should be employed. Correct dehydra-
tion, electrolyte imbalance, hepatic coma and hypotension by established procedures. If required, give oxygen or arterial pressure for respiratory support. The degree to which chlorothiazide sodium is removed by hemodialysis has not been established. The intravenous dose of chlorothiazide in the mouse is 1.1 g/kg.

DOSE AND ADMINISTRATION

Chlorothiazide Sodium for injection should be reserved for patients unable to take oral medication or for emergency situations. Therapy should be individualized according to patient response. Use the smallest dosage necessary to achieve the required response. Intravenous use in infants and children has been limited and is not generally recommended.

When medication can be taken orally, therapy with Chlorothiazide tablets or oral suspension may be substi-
tuted for intravenous therapy, using the same dosage schedule as for the parenteral route.

Chlorothiazide Sodium for injection may be given by slow direct intravenous injection or by intravenous infusion.

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 azotemia. Cumulative effects of the drug may develop in patients with-insufficient renal function.

Thiazides should be used with caution in patients with impaired hepatic function or progressive liver dis-
ease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma. Thi-
azides may add or potentiate the action of other antihypertensive drugs.

Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma.

Thiazides have been shown to increase the urinary excretion of magnesium; this may result in hypomag-
esemia. Whenever adverse reactions are moderate or severe, thiazide dosage should be reduced or therapy with-
drawn. To report SUSPECTED ADVERSE REACTIONS, contact Akorn, Inc. at 1-800-922-5676 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE

The most common signs and symptoms observed are those caused by electrolyte depletion (hyponatremia, hy-
pokalemia, hypochloremia, hypernatremia) and dehydration resulting from excessive diuresis. If diabetics has also been administered, hyponatremia may accentuate cardiac arrhythmias. In the event of overdose, symptomatic and supportive measures should be employed. Correct dehydra-
tion, electrolyte imbalance, hepatic coma and hypotension by established procedures. If required, give oxygen or arterial pressure for respiratory support. The degree to which chlorothiazide sodium is removed by hemodialysis has not been established. The intravenous dose of chlorothiazide in the mouse is 1.1 g/kg.

DOSE AND ADMINISTRATION

Chlorothiazide Sodium for injection should be reserved for patients unable to take oral medication or for emergency situations. Therapy should be individualized according to patient response. Use the smallest dosage necessary to achieve the required response. Intravenous use in infants and children has been limited and is not generally recommended.

When medication can be taken orally, therapy with Chlorothiazide tablets or oral suspension may be substi-
tuted for intravenous therapy, using the same dosage schedule as for the parenteral route.

Chlorothiazide Sodium for injection may be given by slow direct intravenous injection or by intravenous infusion.

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 azotemia. Cumulative effects of the drug may develop in patients with-insufficient renal function.

Thiazides should be used with caution in patients with impaired hepatic function or progressive liver dis-