Intravenous Sodium Diuril® (chlorothiazide sodium) is indicated as adjunctive therapy in edema associated with congestive heart failure, hepatic cirrhosis, and corticosteroid and estrogen therapy.

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

Sodium Diuril (chlorothiazide sodium) is contraindicated in anuria and hypersensitivity to any component of this product or to other sulfonamide-derived drugs.

Available direct or through your authorized wholesaler or distributor.

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**Sodium Diuril® (chlorothiazide sodium)**

**INDICATIONS:**

Intravenous Sodium Diuril® (chlorothiazide sodium) is indicated as adjunctive therapy in edema associated with congestive heart failure, hepatic cirrhosis, and corticosteroid and estrogen therapy.

**USE:**

Intravenous Sodium Diuril® (chlorothiazide sodium) is useful in edema due to various forms of renal dysfunction such as nephrotic syndrome, acute glomerulonephritis, and chronic renal failure.

**CONTRAINDICATIONS:**

Sodium Diuril (chlorothiazide sodium) is contraindicated in anuria and hypersensitivity to any component of this product or to other sulfonamide-derived drugs.

**AVAILABILITY:**

Available direct or through your authorized wholesaler or distributor.

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**DESCRIPTION:**

- **NDC #:** 76478-711-40
- **Unit of Sale:** 0.5 g Lyophilized White Powder Vial
- **Orange Book Code:** AP

**EACH VIAL CONTAINS:**

- **Active:** Chlorothiazide Sodium equivalent to Chlorothiazide 0.5 g.
- **Preservative:** None;
- **Inactives:** Mannitol 0.25 g and Sodium Hydroxide to adjust pH.
- **Storage:** Store at 20-25°C (68-77°F)

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Not for Prescribing Purposes. Please Refer to Package Insert for Full Prescribing Information.
Intravenous Sodium Diuril® (chlorothiazide sodium)

**DESCRIPTION**

Intravenous Sodium DIURIL® (chlorothiazide sodium) is a diuretic and anti-hypertensive. It is 6-chloro-2H-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide. Its empirical formula is C7H6 ClN 3 O4 S2 and its structural formula is:

![Structural formula of chlorothiazide](image)

It is a white, or practically white, crystalline powder with a molecular weight of 285.72, which is very slightly soluble in water, but readily soluble in dilute alkaline solutions. Chlorothiazide sodium contains about 0.7% of sodium and the equivalent of 156.8 mg of chlorothiazide and 22.5 mg of sodium per gram of its anhydrous powder. Chlorothiazide sodium is slightly hygroscopic and dissolves in water to give solutions that are stable.

**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, and of the plasma chlorothiazide 45-120 hours. Chlorothiazide crosses the placental but not the blood-brain barrier and is excreted in breast milk.

**CLINICAL PHARMACOLOGY**

The diuretic effect of thiazide diuretics is the result of inhibition of tubular reabsorption of sodium and chloride in approximately equivalent amounts. Natriuresis may be accompanied by an increase in the secretion of potassium and bicarbonate.

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

**INDICATIONS AND USES**

Intravenous Sodium DIURIL® is indicated as adjunctive therapy in edema associated with congestive heart failure, hepatic cirrhosis, and corticosteroid and estrogen therapy.

**USE IN PREGNANCY**

Routine use of diuretics during normal pregnancy is inappropriate and exposes mother and fetus to unnecessary hazards. Diuretics do not prevent pre-eclampsia or 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 increase in capillary permeability and congestion of pregnancy. Thiazides are indicated in pregnancy when edema is due to pathologic causes, just as they are in the ambulatory pregnant not in toxemia of pregnancy. Dependent edema in pregnancy, resulting from restriction of venous return by the gravid uterus, is properly treated through elevation of the lower extremities and use of support hose. Use of diuretics to lower intravascular volume in this instance is illegal and unnecessary. During normal pregnancy there is hyperhydration which is not harmful to the fetus or the mother in the absence of cardiocavascular pathology. However, it may be associated with edema, rarely generalized edema. If such edema causes discomfort, increased racemurcency will often provide relief. Rarely 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**

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, thiurdzyd diuretics are usually ineffective unless dilutional factors have been corrected. Such patients should be closely observed, as diuretic effects may be greater than anticipated with the drug and circulatory collapse may occur. If edema persists, even after maximal diuretic therapy, sodium and water restriction should be employed. When diuretics are used in patients with impaired renal function, thiazide diuretics should be used with caution in patients with impaired renal function. Thiazide diuretics can precipitate azotemia. Cumulative effects of the drug may develop in patients with impaired renal function.

**CONTRAINDICATIONS**

Lithium should not be given with diuretics (see PRECAUTIONS, Drug Interactions).

**PRECAUTIONS**

Drug Interactions

The antihypertensive effects of the drug may be enhanced in the postsympathetic state. If progressive renal impairment becomes evident, consider withholding or discontinuing the drug.

Thiazides have been shown to increase the urinary excretion of magnesium; this may result in hypomagnesemia. Thiazides may increase serum triglyceride excretion. Thiazides may cause intercurrent and slight elevation of serum calcium in the absence of known disorders of calcium metabolism. Marked hyperglycemia may be evidence of hypovolemia and should be discontinued before carrying out tests for parathyroid function.

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

Periodic determination of serum electrolytes to detect possible electrolyte abnormalities should be done at appropriate intervals.

Drug Interactions

When given concurrently the following drugs may interact with thiazide diuretics:

1. Alcohol, corticosteroids, or narcotics - potentiation of orthostatic hypotension may occur.
2. Adrenergic agents - (oral and insulin) - dosage adjustment of the adrenergic drug may be required.
3. Other antihypertensive agents - additive effect or potentiation of thiazide diuretic action.
4. Corticosteroids, ACTH - intensified electrolyte depletion, particularly hypokalemia.
5. Potassium-sparing diuretics - possible decrease in response to potassium-sparing diuretics.
6. Calcium-sparing diuretics - decreased urinary calcium excretion.
7. Thiazide diuretics can potentiate the hypoglycemic effect of oral hypoglycemic drugs.

**ADVERSE REACTIONS**

The following adverse reactions have been reported and, within each category, are listed in approximate order of decreasing severity.

Body as a Whole: Rash.

Cardiovascular: Hypotension (may be aggravated by alcohol, barbiturates, narcotics or antihypertensive drugs).

CNS: Headache, dizziness, malaise, drowsiness, fatigue, insomnia, mental depression, nervousness.

Gastrointestinal: Nausea, vomiting, anorexia, appetite loss, constipation, diarrhea, flatulence, abdominal cramps.

Hematologic: Agranulocytosis, agranulocytosis, leukopenia, hemolytic anemia, thrombocytopenia.

Hepatobiliary: Jaundice, cholestasis, hepatitis.

Hypersensitivity: Anaphylactic reactions, rashes, urticaria, angioneurotic edema, asthma.

Metabolic: Hyperglycemia, glycosuria.

Musculoskeletal: Muscle cramps, muscle weakness.

Neuromuscular & skeletal: Myalgia.

Renal: Renal failure, interstitial nephritis, nephrotic syndrome.

Respiratory: Cyanosis, respiratory depression, respiratory infection.

Skin: Urticaria, edema, angioneurotic edema, skin rash, necrotizing angiitis (vasculitis and eosinophilia). A lupus-like syndrome, including fever, rash, discoid rash, and photosensitivity.

Other: Hypokalemia.

**OVERDOSAGE**

The most common signs and symptoms observed are those caused by electrolyte and fluid imbalance.

**DOSAGE AND ADMINISTRATION**

Intravenous Sodium DIURIL should be reserved for patients unable to take other means of diuretic therapy, i.e., administration on alternate days or every third day.

**Directions for Reconstitution**

Use aseptic technique. Because Intravenous Sodium DIURIL contains no preservatives, the drug should not be reconstituted more than 24 hours prior to each administration, and the unused portion should be discarded.

**HOW SUPPLIED**

Intravenous Sodium DIURIL is a sterile, light yellow to white powder usually in form of powder, supplied in vials containing chlorothiazide sodium equivalent to 1.1 g/kg.

**ADDITIONAL INFORMATION**

The usual adult dosage is 0.5 to 1 g once or twice a day. Many patients with congestive heart failure and edema respond well to a single daily dose, and most do not require more than two to three doses a day. With the intermediate schedule, excessive response and the resulting undesirable electrolyte imbalance are less likely to occur.

**HOW TO ADMINISTER**

For single dose only. Use solution immediately after reconstitution (see PRECAUTIONS). Discard unused portion of the reconstituted solution.

Deep intravenous injection in the upper outer quadrant of the buttock is recommended.

**INDICATIONS AND USES**

Intravenous Sodium DIURIL is a sterile, lyophilized white powder usually in form of powder, supplied in vials containing chlorothiazide sodium equivalent to 0.5 g of chlorothiazide.

**REFERENCES**

® Registered trademark of Merck & Co., Inc.

Whitehouse Station, NJ 08889, U.S.A.

Calculations based on a human body weight of 50 kg.

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