**WARNINGS**

**Drug Interactions: Ethacrynate sodium may increase the ototoxic potential of other drugs (see PRECAUTIONS, Special Hazards of Systemic Administration).**

Deafness has been reported in patients receiving treatment with ethacrynate sodium. The deafness has usually been reversible and of short duration (one to 24 hours). However, in a few patients, this diuretic has produced severe, watery diarrhea. If this occurs, it should be discontinued and not used again.

**Contraindications:**

All diuretics, including ethacrynate sodium, are contraindicated in anuria. If increasing electrolyte imbalance, azotemia, and/or pulmonary edema, or when gastrointestinal absorption is impaired or oral medication is not practicable.

4. Intravenous ethacrynate sodium is indicated when a rapid onset of diuresis is desired, e.g., in acute pulmonary edema, or when gastrointestinal absorption is impaired or oral medication is not practicable.

**Drug Interactions:**

Ethacrynate sodium may increase the ototoxic potential of other drugs (see PRECAUTIONS, Special Hazards of Systemic Administration).

Deafness has been reported in patients receiving treatment with ethacrynate sodium. The deafness has usually been reversible and of short duration (one to 24 hours). However, in a few patients, this diuretic has produced severe, watery diarrhea. If this occurs, it should be discontinued and not used again. All diuretics, including ethacrynate sodium, are contraindicated in anuria. If increasing electrolyte imbalance, azotemia, and/or pulmonary edema, or when gastrointestinal absorption is impaired or oral medication is not practicable.

**Drug Interactions:**

Ethacrynate sodium may increase the ototoxic potential of other drugs (see PRECAUTIONS, Special Hazards of Systemic Administration).

Deafness has been reported in patients receiving treatment with ethacrynate sodium. The deafness has usually been reversible and of short duration (one to 24 hours). However, in a few patients, this diuretic has produced severe, watery diarrhea. If this occurs, it should be discontinued and not used again. All diuretics, including ethacrynate sodium, are contraindicated in anuria. If increasing electrolyte imbalance, azotemia, and/or pulmonary edema, or when gastrointestinal absorption is impaired or oral medication is not practicable.

4. Intravenous ethacrynate sodium is indicated when a rapid onset of diuresis is desired, e.g., in acute pulmonary edema, or when gastrointestinal absorption is impaired or oral medication is not practicable.
Ethyacrynic acid sodium should be administered as a single intravenous infusion. Single intravenous doses of Ethacrynic Acid Tablets USP of 25, 50, or 75 mg increments, to avoid electrolyte depletion. Rarely, patients who failed to respond to ethacrynic acid have responded to Ethacrynic Acid Tablets USP, for the maintenance of basal weight. The intermittent use of Ethacrynic Acid Tablets USP orally may eliminate the need for the intermittent use of diuretics other than Ethacrynic Acid Tablets USP. Ethacrynic Acid Tablets USP is a solid oral dosage form containing 25 mg, 50 mg or 75 mg of ethacrynic acid, and is indicated for the treatment of edema associated with heart failure, hepatic cirrhosis, hypoproteinemia, or any other cause. The effectiveness was observed between these subjects and younger subjects, and other reported clinical experience has not shown any overall difference in safety or effectiveness between these subjects and younger subjects. The safety and effectiveness in patients who are 75 years of age and over have not been established.

In the event of overdosage, symptomatic and supportive measures should be employed. Emesis should be induced or gastric irrigation performed. Treatment of hypokalemia should be instituted. Symptomatic and supportive measures should be used.

Overdosage

OVERDOSAGE

If overdosage occurs, symptomatic and supportive measures should be employed. Emesis should be induced or gastric irrigation performed. Treatment of hypokalemia should be instituted. Symptomatic and supportive measures should be used.

To report SUSPECTED ADVERSE REACTIONS, contact Par Pharmaceutical, Inc. at 1-800-828-9393 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Skin rash, fever, chills, hematuria.

Headache, fatigue, apprehension, confusion.

Central Nervous System

Rhabdomyolysis has been reported rarely. Reye's syndrome has been reported rarely. Hemolytic-uremic syndrome has been reported rarely. Aplastic anemia has been reported rarely. Acute renal failure has been reported rarely.

Bleeding has occurred in some patients. Thrombocytopenia has been reported rarely. Thrombotic thrombocytopenic purpura has been reported rarely in patients with disseminated intravascular coagulation. Henoch-Schönlein purpura has been reported rarely in patients with disseminated intravascular coagulation. Intravascular coagulation has been reported rarely. Reversible hyperuricemia and acute gout have been reported. Acute symptomatic hypoglycemia with convulsions occurred rarely. Acute pancreatitis has been reported rarely.

Anorexia, malaise, abdominal discomfort or pain, dysphagia, nausea, vomiting, and diarrhea have occurred. These are symptoms of the underlying disease. They occur in some patients treated with Ethacrynic Acid Tablets USP.

InTRaVenous USE

Intravenous Use

Intravenous ethacrynate sodium is for intravenous use when oral intake is impractical or in urgent conditions, such as acute pulmonary edema.

The chloruretic effect of this agent may give rise to retention of bicarbonate and a metabolic alkalosis. This may be corrected by giving sodium bicarbonate or sodium carbonate. Both agents are alkaline and should be administered cautiously in renal insufficiency.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.

It is usually possible to reduce the dosage and frequency of administration once the dry weight has been achieved.