In a few patients this diuretic has produced severe, watery diarrhea. If this occurs, it should be discontinued and not used again.

In patients with renal insufficiency, including those with treated diabetes, the diuretic should be discontinued if oliguria occurs during treatment of severe, progressive renal disease, the diuretic should be discontinued.

All diuretics, including ethacrynic acid, are contraindicated in anuria. If increasing electrolyte imbalance, azotemia, and/or oliguria develop, or if the patient's condition deteriorates, the diuretic should be discontinued.

The diuretic should be discontinued in patients who have received ethacrynate sodium for at least 3 days and who develop a syndrome resembling syndrome of inappropriate antidiuretic hormone (SIADH) manifested by increased urine output and increased serum osmolality.

A number of deaths, primarily due to cardiorespiratory and CNS depression, have been observed in patients treated with ethacrynate sodium. Although some of these deaths may have been due to the underlying disease, contributors to the deaths have included complications of the diuretic therapy.

During therapy with ethacrynate sodium, liberalization of salt intake and supplementary potassium chloride are often necessary.

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Supplemental potassium chloride is administered to prevent or correct the development of hypokalemia. The dosage of potassium chloride may be determined by serum potassium determinations and the rate of change of serum potassium. When potassium is administered, the serum electrolyte levels are carefully monitored and the dosage adjusted accordingly. Potassium chloride is administered orally or parenterally, as directed.

In patients with severe cardiac disease, the diuretic should be given with caution and only when the benefits are likely to outweigh the risks.

The patient's electrolyte levels should be monitored closely during the early phase of treatment and periodically thereafter during the period of diuretic therapy. The patient's electrolyte levels should be monitored closely during the early phase of treatment and periodically thereafter during the period of diuretic therapy.

Potassium depletion is the most common complication of diuretic therapy, and the use of salt-poor albumin should be considered.

Orthostatic hypotension may occur in patients receiving other antihypertensive agents when given ethacrynate acid. Orthostatic hypotension may occur in patients receiving other antihypertensive agents when given ethacrynate acid.

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In the mouse, the oral LD50 of ethacrynic acid is 627 mg/kg and the intravenous LD50 of ethacrynate sodium is 175 mg/kg.

Overdosage may lead to excessive diuresis with electrolyte depletion and dehydration.

OVERDOSAGE

1088 or www.fda.gov/medwatch.

For medical advice about adverse reactions contact your medical professional.

Ethacrynate sodium occasionally has caused local irritation and pain after intravenous use.

Headache, fatigue, apprehension, confusion.

Agranulocytosis or severe neutropenia has been reported in a few critically ill patients also receiving agents known to produce

and abnormal liver function tests have been reported in seriously ill patients receiving multiple drug therapy, including

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Gastrointestinal

ADVERSE REACTIONS

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in

identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals

ADMINISTRATION,

There are no well-controlled clinical trials in pediatric patients.

discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

There are, however, no adequate and well-controlled studies in pregnant women. Since animal reproduction studies are not

In a two-litter study in the dog and rat, oral doses of 5 or 20 mg/kg/day (2½ or 10 times the human dose), respectively, did not

abnormalities of the fetus due to ethacrynate sodium.

Ethacrynic acid had no effect on fertility in a two-litter study in rats or a two-generation study in mice at 10 times the human

Dosage must be regulated carefully to prevent a more rapid or substantial loss of fluid or electrolyte than is indicated

Store in a tightly closed container between 20° to 25°C (68° to 77°F). (See USP Controlled Room Temperature.)

HOW SUPPLIED

The solution may be given slowly through the tubing of a running infusion or by direct intravenous injection over a period of

Occasionally, some 5 percent Dextrose Injection solutions may have a low pH (below 5). The resulting solution with such

A single intravenous dose not exceeding 100 mg has been used in critical situations.

The usual intravenous dose for the average sized adult is 50 mg, or 0.5 to 1 mg per kg of body weight. Usually only one dose

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

Salt liberalization usually prevents the development of hyponatremia and hypochloremia. During treatment with Ethacrynic

or both, during treatment with Ethacrynic Acid Tablets USP is advisable, especially in cirrhotic or nephrotic patients and in

While many patients do not require supplemental potassium, the use of potassium chloride or potassium-sparing agents,

Ethacrynic Acid Tablets USP has additive effects when used with other diuretics. For example, a patient who is on

Ethacrynic Acid Tablets USP may be given intermittently after an effective diuresis is obtained with the regimen outlined

If the patient should be unable to take the drug by mouth, multiple doses of 25 to 50 mg increments to avoid derangement of water and electrolyte excretion.

From 50 to 200 mg daily) may be given on a continuous or intermittent dosage schedule. Dosage adjustments are usually in

of diuresis usually occurs at 50 to 100 mg for adults. After diuresis has been achieved, the minimally effective dose (usually

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

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The patient should be weighed under standard conditions before and during the institution of diuretic therapy with this

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