Fosinopril Sodium and Hydrochlorothiazide Tablets, USP
Rx only

**INDICATIONS AND USAGE**

This drug is indicated for the treatment of hypertension in adults.

**CONTRAINDICATIONS**

Hydrochlorothiazide is contraindicated in patients who are hypersensitive to this drug. Fosinopril is contraindicated in patients with a history of angioedema due to an angiotensin-converting enzyme (ACE) inhibitor or who have ever had a run-in with the drug. Other contraindications include pregnancy, lactation, and hypersensitivity reactions to other ACE inhibitors.

**WARNINGS**

Hypotension

Hypotension may occur after the initial dosages of either component of this combination product. Since both components may potentiate hypotensive effects, it is recommended that all patients be started on the smallest effective dosage of both components.

Hypertension

The hypotensive effects of any ACE inhibitor are potentiated by diuretics, particularly the thiazides. In patients treated with concomitant diuretics and ACE inhibitors, caution should be exercised in determining the initial dosage levels of both components. The hypotensive effects of an ACE inhibitor can be reversed by large parenteral volumes of normal saline. When used in combination with other antihypertensive agents, therapy should begin at the least effective doses. The use of a diuretic, particularly in patients with heart failure or renal insufficiency, is recommended in the initial management of hypertension.

**PRECAUTIONS**

Angioedema

Angioedema has occurred in patients treated with fosinopril. Angioedema, including fatal cases, has been reported in association with ACE inhibitors. Patients with a history of angioedema due to other ACE inhibitors should not be treated with this drug. If angioedema occurs, the drug should be discontinued immediately and appropriate therapy should be initiated. Close observation should continue until the edema has resolved.

**ADVERSE REACTIONS**

The adverse reactions of this combination product are those expected from the use of fosinopril and hydrochlorothiazide alone. The most common adverse reactions are dizziness, headache, and gastrointestinal disturbances. Other adverse reactions may include cough, rash, and interstitial nephritis.

**DOSE AND ADMINISTRATION**

The initial dose of fosinopril is 10 mg and the initial dose of hydrochlorothiazide is 25 mg. The dose may be increased at weekly intervals, if necessary, to a maximum of 40 mg of fosinopril and 50 mg of hydrochlorothiazide daily. The dose of fosinopril may be increased to 20 mg and the dose of hydrochlorothiazide to 100 mg daily if necessary. The dosages of fosinopril and hydrochlorothiazide should not exceed 40 mg and 100 mg daily, respectively.

**OVERDOSAGE**

When the patient is overdosed with both components of this combination product, supportive therapy should be provided. Discontinue the drug and institute supportive and symptomatic treatment measures. In case of severe hypotension, large parenteral volumes of normal saline should be administered. If cardiac output fails to improve, a dopamine infusion may be necessary. In case of severe renal failure, hemodialysis or peritoneal dialysis may be necessary. If hypokalemia occurs, potassium supplements should be administered. If cardiac arrhythmias occur, appropriate treatment should be given. In case of severe angioedema, discontinue fosinopril and hydrochlorothiazide and institute appropriate therapy. If toxicity occurs, consider gastrointestinal decontamination, if feasible, with gastric lavage or emesis.
DOSAGE AND ADMINISTRATION

Store at

HOW SUPPLIED

Framiparox Sodium Tablets 5 mg, 10 mg, and 15 mg are supplied in bottles of 60. Bottles of 60 Tablets

BASED ON THE PRELIMINARY CLINICAL DATA OF DOXORUBICIN/HIT, DOXORUBICIN/HIT WITH FOLINTANDRINE/SUTISM,

Framiparox Sodium Tablets 5 mg, 10 mg, and 15 mg are supplied in bottles of 60. Bottles of 60 Tablets

Bottles of 60

DOXORUBICIN/HIT, DOXORUBICIN/HIT WITH FOLINTANDRINE/SUTISM,

Framiparox Sodium Tablets 5 mg, 10 mg, and 15 mg are supplied in bottles of 60. Bottles of 60 Tablets

Bottles of 60

DOXORUBICIN/HIT, DOXORUBICIN/HIT WITH FOLINTANDRINE/SUTISM,

Framiparox Sodium Tablets 5 mg, 10 mg, and 15 mg are supplied in bottles of 60. Bottles of 60 Tablets

Bottles of 60

DOXORUBICIN/HIT, DOXORUBICIN/HIT WITH FOLINTANDRINE/SUTISM,