

Fusid[®]

Furosemide

COMPOSITION

Fusid[®] 40 tablet: Each tablet contains Furosemide BP 40 mg.

Fusid[®] injection: Each 2 ml ampoule contains Furosemide BP 20 mg.

PHARMACOLOGY

Fusid[®] (Furosemide) is a monosulphonyl diuretic. It is an effective diuretic that retains its activity even in low glomerular filtration rate (GFR). **Fusid[®]** has a distinctive action on renal tubular function. It affects a peak diuresis far greater than that observed with other agents. Other features are (I) prompt onset of action (II) inhibition of sodium and chloride transport in the ascending limb of the loop of Henle and (III) independence of their action from acid-base balance changes. **Fusid[®]** acts primarily to inhibit electrolyte reabsorption in the thick ascending limb of the loop of Henle. Furosemide is readily absorbed from the gastrointestinal tract and considerable proportions are bound to plasma proteins. It is rapidly excreted in the urine. With an hour after intravenous injection, its effect is evident in about 5 minutes and last for about 2 hours.

INDICATION

Fusid[®] is a diuretic recommended for use in all indications when a prompt and effective diuresis is required. Indications for **Fusid[®]** tablet 40 mg include cardiac, pulmonary, hepatic and renal oedema, peripheral edema due to mechanical obstruction or venous insufficiency and hypertension.

Injection:

Fusid[®] is a diuretic recommended for use when a prompt and effective diuresis is required. The intravenous formulation is appropriate for use in emergencies or when oral therapy is precluded. Indications include cardiac, pulmonary, hepatic and renal oedema.

DOSAGE AND ADMINISTRATION

Fusid[®] 40 Tablet

Edema: Adults: The initial adult dose is 40mg daily, reduced to 20mg daily or 40mg on alternate days. In some patients daily doses of 80mg or higher (given in divided doses) may be required. The individually determined single dose should then be given once or twice daily (eg, at 8 am and 2 pm). For resistant edema, 80-120 mg daily. In patients with clinically severe edematous states the dose of furosemide may be carefully titrated up to 600 mg/day. When doses exceeding 80 mg/day are given for prolonged periods, careful clinical observation and laboratory monitoring are particularly advisable.

Children: Neonate: 0.5–2 mg/kg every 12–24 hours (every 24 hours if postmenstrual age under 31 weeks).

Child 1 month–12 years: 0.5–2 mg/kg 2–3 times daily (every 24 hours if postmenstrual age less than 31 weeks); higher doses may be required in resistant edema; max. 12 mg/kg daily, not to exceed 80 mg daily.

Child 12–18 years: 20–40 mg daily, increased in resistant edema to 80–120 mg daily.

Elderly: In the elderly furosemide is generally eliminated more slowly. Dosage should be titrated until the required response is achieved.

Hypertension: Adults: The usual initial dose of furosemide for hypertension is 80 mg, usually divided into 40 mg twice a day. Dosage should then be adjusted according to response. If response is not satisfactory, add other antihypertensive agents.

Children: The usual dose is 1 - 3 mg/kg body weight daily up to a maximum dose of 40mg/day.

Elderly: In the elderly furosemide is generally eliminated more slowly. Dosage should be titrated until the required response is achieved.

Fusid[®] Injection

Edema: Adults: Doses of 20-50 mg intramuscularly or intravenously may be given initially. If larger doses are required, they should be given increasing by 20 mg increments and not given more often than every two hours. If doses greater than 50 mg are required it is recommended that they should be given by slow intravenous infusion. The recommended maximum daily dose of furosemide administration is 1,500 mg.

Children:

By slow intravenous injection

Neonate: 0.5–1 mg/kg every 12–24 hours (every 24 hours if

postmenstrual age under 31 weeks).

Child 1 month–12 years: 0.5–1 mg/kg repeated every 8 hours as necessary; maximum 2 mg/kg (max. 40 mg) every 8 hours.

Child 12–18 years: 20–40 mg repeated every 8 hours as necessary; higher doses may be required in resistant cases.

By continuous intravenous infusion

Child 1 month–18 years: 0.1–2 mg/kg/hour (following cardiac surgery, initially 100 micrograms/kg/hour, doubled every 2 hours until urine output exceeds 1 mL/kg/hour).

Elderly: In the elderly furosemide is generally eliminated more slowly. Dosage should be titrated until the required response is achieved.

Hypertension: Adults: Doses of 20 to 50 mg intramuscularly or intravenously may be given initially. If larger doses are required, they should be given increasing by 20 mg increments and not given more often than every two hours.

If doses greater than 50 mg are required it is recommended that they should be given by slow intravenous infusion. The recommended maximum daily dose of furosemide administration is 1,500 mg. Children: Parenteral doses for children range from 0.5-1.5 mg/kg body weight daily up to a maximum total daily dose of 20 mg.

Elderly: In the elderly furosemide is generally eliminated more slowly. Dosage should be titrated until the required response is achieved.

CONTRAINDICATION AND PRECAUTION

Furosemide is contraindicated in anuria, electrolyte deficiency and pre-comatose states associated with liver cirrhosis. Hypersensitivity to furosemide or sulphonamides.

Patients with prostatic hypertrophy or impairment of micturition have an increased risk of developing acute retention. A marked fall in blood pressure may be seen when ACE inhibitors are added to furosemide therapy. The toxic effects of nephrotoxic antibiotics may be increased by concomitant administration of potent diuretics such as furosemide.

SIDE EFFECT

As with other diuretics, electrolytes and water balance may be disturbed as a result of diuresis of prolonged therapy. Prolonged use can produce alkalosis. It may also cause uric acid retention and may rarely produce acute gout. Furosemide may provoke hyperglycemia and glycosuria.

DRUG INTERACTION

A marked fall in blood pressure may be seen when ACE inhibitors are added to furosemide therapy. Serum lithium levels may be increased when lithium is given concomitantly with furosemide. The toxic effects of nephrotoxic antibiotics may be increased by concomitant administration of potent diuretics such as furosemide.

USE IN PREGNACY AND LACTATION

Pregnancy category C.

Furosemide should be cautiously used in cardiogenic shock complicated by pulmonary oedema and in the first trimester of pregnancy. Blood pressure and pulse during rapid diuresis should be monitored. Caution should be observed in patients liable to electrolyte deficiency. In case of nursing mother, furosemide may inhibit lactation or may pass into breast milk. In that case it should be used with caution.

STORAGE CONDITION

Fusid[®] 40 tablet/injection should be protected from light and moisture, stored in a cool dry place.

HOW SUPPLIED

Fusid[®] 40 tablet: Each box contains 200 tablets in Alu-PVC blister pack.

Fusid[®] injection: Each box contains 10 ampoules in Alu-PVC blister pack.

Manufactured by:



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