

DIRINE

DIRINE INJECTION 20 MG/2 ML



Name and Strength of Active Substance(s):-

Furosemide Injection 20 mg/2 ml

Product Description:-

DIRINE INJECTION is clear colorless sterile mobile liquid of furosemide fill in amber glass ampoule.

Pharmacodynamics:-

Furosemide is a loop diuretic which reduces the resorption of electrolytes by the proximal and distal renal tubules and by the loop of Henle. Excretion sodium, potassium and chloride ions are increased and as a consequence water excretion is enhanced. It has no effect on carbonic anhydrase in the renal tubular cells and urinary pH during the phase of diuresis may be increased after administration of furosemide. Furosemide is rapidly absorbed when given by mouth and provokes an intense diuresis lasting for 4 to 6 hours. This initial diuresis is greater than with the equivalent thiazide derivatives, although volume of fluid excreted over a period of 24 hours may not be greatly different. Furosemide is used for the treatment of the same conditions as chlorothiazide. It may be effective when tolerance to thiazide diuretics has developed. Its action is not enhanced by thiazides. Its onset is rapid, with 30 minutes of oral administration, intense and of short duration. Once diuresis is adequately established furosemide dosage may be reduced for management purposes. Furosemide is also used in doses of up to 2 grams by injection or infusion for the prophylaxis of incipient and the treatment of established acute renal failure. Furosemide enhances the effects of hypotensive drugs and the dose of these may have to be adjusted to suit the need of the patient when given concurrently for the control of mild or moderate hypertension. In cerebral oedema. It is given by intravenous injection and produces effects comparable with those following intravenous infusion of cosmetically active substances.

Pharmacokinetics:-

Furosemide is rapidly absorbed from the side of injection. In subjects without cardiac or renal diseases, peak plasma concentration are attained in about 30 minutes. Plasma half-life after intravenous administration is about 30 minutes. In subjects with advanced renal failure, the plasma half-life is about 10 hours. In patients with renal failure and liver disease, the half-life may be as long as 20 hours. High concentrations are found in the liver and the kidneys, volume of distribution is about 11.4% of the body weight which may be increased in patients with advanced renal failure to about 17.8% of body weight. About 95% is bound to plasma proteins. The metabolites are mainly 4-chloro-5-sulphamoylanthranilic acid and conjugates of glucuronic acid. After an oral dose, 20 to 55% excreted in the urine in 24 hours and about 2% excreted in the feces. After intramuscular or intravenous administration 70% to 90% is excreted in the urine. The unchanged drug and 4-chloro-5-sulphamoylanthranilic acid are detectable in the urine.

Indications:-

Edema of renal origin, cardiac edema which cannot be adequately managed by glycoside treatment. Ascites due to cirrhosis of the liver, mechanical obstruction of cardiac failure peripheral edema, edema due to burns, pregnancy edema after 6 months, eclampsia, pulmonary edema, cerebral edema, mild or moderate hypertension, barbiturate poisoning.

Recommended dosage:-

Usual dose intramuscular or intravenous: 20 mg to 40 mg. If necessary, after not less than 2 hours, increase by 20 mg until desired effect is attained. Usual dosage range, 20 mg to 1g daily. Intravenous administration should be given slowly. In the treatment of acute or chronic renal failure, Dirine Injection is given by infusion over 1 hours followed, if urine output is insufficient within the next hour by 500 mg in 450 ml infused over 2 hours and subsequently by 1g in 400 ml over 4 hours. If the response is satisfactory, the effective dose of up to 1g may be given daily or treatment may be maintained by mouth. 500 mg by mouth should

be given for each 250 mg dose by injection. Furosemide had given in acute hypertensive crisis intravenously in doses of 100 to 200 mg over 1 to 2 minutes. Furosemide is also used in doses of up to 2 g by injection or infusion for the prophylaxis of incipient and the treatment of established acute renal failure. The usual dosage for children is 1 to 3 mg per kilogram body weight daily by mouth or 0.5 to 0.15 mg per kilogram bodyweight daily by injection.

Route of administration:

Intramuscular or Intravenous.

Contraindications:-

Acute renal failure with anuria, hepatic coma, impaired liver function and gout.

Warnings and precautions:

As with chlorothiazide treatment, potassium depletion may occur when treatment with furosemide is prolonged. Potassium supplements should be given.

Interaction with other medicaments:-

Not applicable.

Pregnancy and lactation:-

Not applicable.

Adverse effects/side effects:-

Electrolyte imbalance, potassium depletion. Prolonged and regular administration may produce hypokalemia. Dehydration.

Overdose and Treatment:

System of electrolyte imbalance or potassium depletion may be treated with supplements. In recent severe overdosage, the stomach should be emptied by aspiration and lavage. Respiration, pulse and blood pressure should be monitored. General supportive measures should be employed along with immediate gastric lavage. Intravenous fluid should be administered and an adequate airway maintained.

Incompatibility:-

Solutions of furosemide for injection are alkaline and should not be mixed or diluted with glucose injection or other acidic solutions.

Furosemide injection has been reported to be visually incompatible with injections of diltiazem hydrochloride, dobutamine hydrochloride, dopamine hydrochloride, labetalol hydrochloride, midazolam hydrochloride, milrinone lactate, nifedipine hydrochloride, and vecuronium bromide. Incompatibility has also been noted with parenteral nutrient solutions, with cisatracurium besilate, with levofloxacin, with phenylephrine, and with vasopressin.

Storage Condition:-

Store in temperature below 30°C

Dosage forms and packaging available:

DIRINE INJECTION are supplied in 2 ml ampoule packing of 25x2 ml per box.

Manufacturer:-

ATLANTIC LABORATORIES CORPORATION LTD.

111, Moo 7, Bang Phli Noi, Bang Bo, Samut Prakan 10560, Thailand.

Product Registration Holder:-

ATLANTIC LABORATORIES (M) SDN. BHD.

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