Burinex®

Short-acting diuretic

TABLETS:
Bumetanide 1 mg and 5 mg.

AMPOULES:
Bumetanide 0.50 mg/ml.

PROPERTIES:
Burinex® is a potent high-ceiling diuretic with a rapid onset and a short duration of action. After oral administration, Burinex® is almost totally absorbed and the diuresis begins within 30 minutes with a peak effect between 1 and 2 hours. After a dose of 1 mg the diuretic effect is virtually complete in 3 hours. This short action minimizes disturbances in the patient's daily routine and allows an individual timing of the diuresis according to the needs of the patient.
Burinex® injection may be administered intramuscularly, intravenously, or as an intravenous infusion. After an intravenous injection, the diuresis starts within a few minutes and ceases in about 2 hours. The diuretic effect of Burinex® is dose-related so that patients, failing to respond to a low initial dose, may respond to higher doses.
Burinex® has been shown to exert its major effect in the ascending limb of the loop of Henle, but it may also have an additional action in the proximal tubule. Clinical investigations have shown that Burinex® is reliably effective and well tolerated.

INDICATIONS:
Burinex® is indicated whenever diuretic therapy is required in the treatment of oedema e.g. associated with congestive heart failure, cirrhosis of the liver, renal diseases including the nephrotic syndrome. Acute pulmonary oedema, druginduced fluid retention, and drug poisoning that can be treated by forced diuresis. Hypertension.

DOSAGE:
Orally: 1 mg daily.
In refractory cases the dose can be increased gradually till a satisfactory response has been obtained. Rarely will it be necessary to exceed a dose of 4 mg daily. The 5 mg tablet is for use in resistant oedema due to renal insufficiency and where higher doses are required. In high dose therapy consideration should be given to a twice daily dosing.
Children: The dose is calculated on the basis of 0.03–0.06 mg/kg daily.
Elderly: Adjust dosage according to response; a dose of 0.5 mg daily may be sufficient in some elderly patients.
Where intramuscular administration is considered appropriate a dose of 1 mg should be given initially and the dose then be adjusted according to the diuretic response.

Parenterally: Usually 1–2 mg intravenously or intramuscularly.
Pulmonary oedema: Initially 2 mg by intravenous injection.
This can be repeated, if necessary, after 20 minutes. In those conditions in which an infusion appropriate, 2–5 mg may be given in 500 ml infusion fluid over 30–60 minutes.
Renal failure: 2–10 mg in 500 ml infusion fluid given over a period of 30–60 minutes. Repeated, if required, at intervals of 6–8 hours.

Drug poisoning with salicylates or barbiturates:
Initially, 2 mg intravenously, followed by 1 mg every 4 hours. Totally, 7 mg in the course of 24 hours. The usual procedure for forced alkaline diuresis should be followed. Burinex® injection may be added to the commonly used infusion fluids based on glucose, sodiumchloride, sodium bicarbonate, or potassium chloride.

CONTRA-INDICATIONS:
Although Burinex® can be used to induce diuresis in renal insufficiency, any marked increase in blood urea or the development of oliguria or anuria during treatment of severe progressing renal disease are indications for stopping treatment with Burinex®. Burinex® is contraindicated in hepatic coma and care should be taken in states of severe electrolyte depletion. As with other diuretics, Burinex® should not be administered concurrently with lithium salts. Diuretics can reduce lithium clearance resulting in high serum levels of lithium.

PRECAUTIONS:
The precautions to be taken with Burinex® – as with other diuretics – are mainly those associated with electrolyte disturbances. Patients with hepatic cirrhosis and patients on digitalis therapy are particularly susceptible to changes in the serum potassium levels. Periodic control of serum electrolytes is, therefore, advisable. Similarly, periodic control of urine and blood glucose is advisable in patients with diabetes and patients suspected of latent diabetes.
Burinex® may potentiate the effect of antihypertensive drugs.

PREGNANCY:
The general principle that drug treatment should be avoided in the 1st trimester of pregnancy is also valid for Burinex® although no teratogenic effects have been observed in animal experiments.

SIDE-EFFECTS:
The incidence of reported side-effects is low. Long-term treatment may provoke changes of the electrolyte balance in the form of hypokalaemia and hypochloraemic alkalosis. In such cases supplementary potassium chloride is recommended. Asymptomatic hyperuricaemia has been observed in some patients. Occasionally, intensive therapy in patients with severe chronic renal failure has been associated with muscular cramps or pain, which have subsided on withdrawal of therapy. Skin rashes, agranulocytosis or thrombocytopenia, and abdominal discomfort has been recorded in a few cases. The ototoxic potential is very low.

OVERDOSAGE:
General measures should be taken to restore blood volume, maintain blood pressure and correct electrolyte disturbance.

STORAGE CONDITIONS:
Store at controlled room temperature (15°C-25°C).

SHELF LIFE:
Burinex® tablets: 5 years.
Burinex® ampoules: 3 years.

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