AMIFRU 40

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.

Abbreviated Prescribing information for AMIFRU 40 (Amiloride and Furosemide Tablets I.P.**)**

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Furosemide is a loop diuretic, which acts primarily to inhibit electrolyte reabsorption in the thick ascending Loop of Henle. Excretion of sodium, potassium and chloride ions is increased and water excretion enhanced. Amiloride is a mild diuretic, which moderately increases the excretion of sodium and chloride and reduces potassium excretion, and appears to act mainly on the distal renal tubules. It does not appear to act by inhibition of aldosterone and does not inhibit carbonic anhydrase. A combination of Furosemide and Amiloride is a diuretic, which reduces the potassium loss of furosemide alone while avoiding the possible gastro-intestinal disturbances of potassium supplements.

DOSAGE AND ADMINISTRATION: One tablet once daily or as directed by physician.

CONTRAINDICATION: Hypersensitivity to furosemide, amiloride, sulphonamides or sulphonamide derivatives, or any of the excipients of the product. In patients with hypovolaemia or dehydration (with or without accompanying hypotension), with an impaired renal function and a creatinine clearance below 30ml/min per 1.73 m^2 body surface area, anuria or renal failure with anuria not responding to furosemide, renal failure as a result of poisoning by nephrotoxic or hepatotoxic agents or renal failure associated with hepatic coma, hyperkalaemia, severe hypokalaemia, severe hyponatraemia, concomitant potassium supplements or potassium sparing diuretics, precomatose states associated with cirrhosis, Addison's disease, and breast feeding women. Amiloride and Furosemide Tablets is contraindicated in children and adolescents under 18 years of age.

WARNINGS & PRECAUTIONS: It should be discontinued before a glucose tolerance test. It should be used with particular caution in patients with potential obstruction of the urinary tract or disorders rendering electrolyte balance precarious, with hypotension, who are at risk from a pronounced fall in blood pressure and in patients where latent diabetes may become manifest or the insulin requirements of diabetic patients may increase, patients with gout, with hepatic cirrhosis together with impaired renal function, with hypoproteinaemia, symptomatic hypotension leading to dizziness, fainting or loss of consciousness can occur in patients treated with furosemide. Caution should be exercised, while using concomitantly with risperidone.

DRUG INTERACTION: Concurrent administration with cardiac glycosides, diuretics, anti-hypertensive agents, or other drugs with blood-pressure-lowering potential may require dose adjustment. When amiloride is taken in combination with potassium salts, with drugs, which reduce potassium excretion, with nonsteroidal anti-inflammatory drugs or with ACE inhibitors, an increase in serum potassium concentration and hyperkalaemia may occur. Risk of ototoxic effects, if cisplatin and furosemide are given concomitantly. Amiloride may cause raised blood digoxin levels. Some electrolyte disturbances (e.g. hypokalaemia, hypomagnesaemia) may increase the toxicity of certain other drugs (e.g. digitalis preparations and drugs inducing QT interval prolongation syndrome). Attenuation of the effect of Amiloride and Furosemide

Tablets may occur following concurrent administration of phenytoin. Concomitant administration of carbamazepine or aminoglutethimide may increase the risk of hyponatraemia. Corticosteroids, carbenoxolone, liquorice, B_2 sympathomimetics in large amounts, and prolonged use of laxatives, reboxetine and amphotericin may increase the risk of developing hypokalaemia, ciclosporin and furosemide is associated with increased risk of gouty arthritis.

ADVERSE REACTIONS: Eosinophilia, haemoconcentration, thrombocytopenia, leucopenia, Bone marrow depression, Paraesthesia, Hepatic encephalopathy, Dizziness, fainting, loss of consciousness and headache, Metabolism and nutrition disorders, Hearing disorders, hypoproteinaemia (e.g. in nephritic syndrome), Tinnitus, hypotension, impairment of concentration and reactions, light-headedness, sensations of pressure in the head, headache, dizziness, drowsiness, weakness, disorders of vision, dry mouth, orthostatic intolerance, Thrombosis, Vasculitis, cholestasis and transaminases increases, skin rashes, photosensitivity, fever or shock, pruritis, urticaria, rashes, dermatitis bullous, erythema multiforme, pemphigoid, dermatitis exfoliative, purpura, photosensitivity, Stevens-Johnson syndrome, toxic epidermal necrolysis, AGEP (acute generalized exanthematous pustulosis) and DRESS (Drug Rash with Eosinophilia and Systemic Symptoms), lichenoid reactions, psychiatric disturbances, Nephrocalcinosis / Nephrolithiasis, patent ductus arteriosus, systemic lupus erythematosus, nausea, malaise or gastric upset (vomiting or diarrhoea) and constipation, Pancreatitis acute may occur.

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Manufactured in India by:
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(Additional information is available on request)