AMIFRU S

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for **AMIFRU S** [Frusemide and Spironolactone Tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: **Furosemide**: Furosemide inhibits primarily the absorption of sodium and chloride not only in the proximal and distal tubules but also in the loop of Henle. Spironolactone is a specific pharmacologic antagonist of aldosterone, acting primarily through competitive binding of receptors at the aldosterone-dependent sodium-potassium exchange site in the distal convoluted renal tubule. Spironolactone causes increased amounts of sodium and water to be excreted, while potassium is retained.

INDICATION: Oedematous states particularly in conditions where potassium ion conservation is important eg: congestive cardiac failure, nephrotic syndrome, ascites associated with liver cirrhosis; mild and moderate degrees of essential hypertension.

DOSAGE AND ADMINISTRATION: One to eight tablets per day, depending on the condition.

CONTRAINDICATION: Hypersensitivity to any of the components of product or furosemide or spironolactone; anuria; acute renal insufficiency, significant impairment of renal excretory function, hyperkalemia, addition's disease, concomitant use of eplerenone.

WARNINGS & PRECAUTIONS: Hepatic coma; severe progressive renal disease; ototoxicity; hyperkalemia; diabetes mellitus; metabolic or respiratory acidosis; volume depleted patients; fluid-electrolyte imbalance; urinary retention; radio contrast nephropathy; hypoproteinemia; hyperuricemia; gout; systemic lupus erythematosus; blood dyscrasias, liver or kidney damage; laboratory analysis (serum electrolytes, CO_2, BUN, creatinine, blood glucose), drugs causing increase potassium level, severe heart failure, dilutional hyponatremia, gynecomastia; **Spironolactone is having tumorigenic potential during chronic toxicity study in rats.**

DRUG INTERACTIONS: Aminoglycosides, ethacrynic acid, high dose of salicylates, cisplatin, tubocurarine, succinyl choline, lithium, ACEIs, ARBs, ganglionic or peripheral adrenergic blocking drugs, sucralfate, chloral hydrate, phenytoin, methotrexate, cyclosporine, tacrolimus, acetylsalicylic acid, NSAIDs, indomethacine, digoxin.

ADVERSE REACTIONS: Hearing loss, ototoxicity, tinnitus, hepatic encephalopathy, hepatocellular insufficiency, pancreatitis, jaundice (intrahepatic cholestatic jaundice), increased liver enzymes, anorexia, oral/gastric irritation, cramping, diarrhea, constipation, nausea, vomiting, severe anaphylactic reactions, paresthesias, vertigo, dizziness, headache, blurred vision, xanthopsia, severe hematopoietic reactions, severe dermatological reactions (SJS, TEN, EM, DRESS, bullous reactions, photosensitivity), orthostatic hypotension, increase TG and cholesterol level, hyperglycemia, glycosuria, hyperuricemia, muscle spasm, weakness, restlessness, urinary bladder spasm, thrombophlebitis, fever, pain, palpitation, arrhythmia, hypotension orthostatic, GI bleeding, confusion, increased intraocular pressure, polyuria, dysuria, impotence arrhythmia, hyperkalemia.

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(Additional information is available on request)