

Fusid[®] Plus

Spirolactone+Frusemide

K⁺ sparing – Loop Diuretic combination

PRESENTATION

Fusid[®] Plus Tablet: Each film coated tablet contains Spirolactone BP 50 mg and Frusemide BP 20 mg.

Fusid[®] 40 Plus Tablet: Each film coated tablet contains Spirolactone BP 50 mg and Frusemide BP 40 mg.

PHARMACOLOGY

Fusid[®] Plus is a combination diuretic containing a loop diuretic, Frusemide and a potassium sparing diuretic, Spirolactone. Spirolactone and Frusemide have different but complimentary mechanisms and sites of action. Therefore, when given together, they produce additive or synergistic diuretic. The Frusemide component inhibits the Na⁺/K⁺/2Cl⁻ cotransporter in the ascending Loop of Henle and blocks the reabsorption of sodium, potassium and chloride ions thereby increasing the quantity of sodium and the volume of water excreted in the urine. This characteristically induces potassium loss. The spironolactone component inhibits the reabsorption of sodium in exchange for potassium at the distal tubule by antagonising the action of aldosterone so that sodium excretion is greatly favoured and the excess loss of potassium, induced by the Frusemide, is reduced.

INDICATIONS AND USES

Essential hypertension, Chronic congestive heart failure, Hepatic cirrhosis with collection of fluid in the abdominal cavity (ascites), Swelling due to excess fluid retention (edema), Hyperaldosteronism, resistant edema associated with secondary hyperaldosteronism.

DOSAGE & ADMINISTRATION

Fusid[®] Plus: 1 to 4 tablets daily (50 to 200 mg of spironolactone and 20 to 80 mg of frusemide) according to the patient's response.

Fusid[®] 40 Plus: For previously stabilised patients requiring higher dosage of spironolactone and frusemide, **Fusid[®] 40 Plus** tablet can be used at a dose of 1 to 2 tablets daily (spironolactone 50 to 100 mg and frusemide 40 to 80 mg).

CONTRAINDICATION

Contraindicated in patients with anuria, acute renal insufficiency, rapidly deteriorating or severe impairment of renal function (creatinine clearance: < 30 ml/min), hyperkalaemia, Addison's disease and in patients who are hypersensitive to spironolactone, frusemide or sulphonamides.

SIDE EFFECT

Spironolactone may give rise to headache and drowsiness and gastrointestinal distress, including cramp and diarrhoea. Ataxia, mental confusion and skin rashes have been reported as side effect. Gynaecomastia is not uncommon and in rare cases breast enlargement may persist. Other endocrine disorders including hirsutism, deepening of the voice, menstrual irregularities and impotence. Transient increase in blood-urea-nitrogen concentrations may occur and mild acidosis has been reported. Spironolactone may cause hyponatremia and hyperkalemia. Excessive diuresis may result in dehydration and reduction in blood volume with circulatory collapse with the possibility of vascular thrombosis and embolism particularly in elderly patients. Serious depletion of potassium and magnesium may lead to cardiac arrhythmias.

PRECAUTION

Caution should be taken in patients liable to electrolyte deficiency. This preparation should also be used with caution in diabetes, enlarged prostate, hypotension and in hypovolemia.

DRUG INTERACTION

When taken together with ACE inhibitors or potassium salts there is an increased risk of hyperkalemia. Spironolactone increases the levels of cardiac glycosides such as digoxin in the blood and this may result in digitalis toxicity. Corticosteroids may cause hypokalemia if they are used with Spironolactone. The blood pressure lowering and diuretic effects of Frusemide may be reduced or abolished when used together with indomethacin and possibly other non-steroidal anti-inflammatory drugs (NSAIDs). Frusemide may increase the ototoxicity of aminoglycoside antibiotics. Simultaneous administration of sucralfate and Frusemide may reduce the natriuretic and anti-hypertensive effect of Frusemide.

USE IN PREGNANCY

Spironolactone and its metabolites may cross the placental barrier. With Spironolactone, feminisation has been observed in male rat foetus. The use of spironolactone in pregnant women requires that the anticipated benefit be weighed against the possible hazards to the mother and foetus. Animal teratology studies indicate that Frusemide may cause foetal abnormalities. Therefore, Frusemide should only be used in women in child bearing age when appropriate contraceptive measures are taken or if the potential benefits justify the potential risks to the foetus.

USE IN LACTATION

Metabolites of Spironolactone have been detected in breast milk. If use of Spironolactone is considered essential, an alternative method of infant feeding should be instituted. Frusemide is excreted in breast milk and breast-feeding should be discontinued if treatment is essential.

USE IN PAEDIATRIC PATIENTS

Spironolactone and Frusemide is not suitable for use in children. Spironolactone and Frusemide may both be excreted more slowly in the elderly.

STORAGE CONDITION

Store at a cool and dry place, protected from light and moisture.

HOW SUPPLIED

Fusid[®] Plus Tablet: Each box contains 3x10 tablets in blister pack.

Fusid[®] 40 Plus Tablet: Each box contains 3x10 tablets in blister pack.

® Registered Trade Mark



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