

# Frusin® Plus

Furosemide + Spironolactone

## Description

Furosemide is a type of medicine called a loop diuretic, and spironolactone is a type of medicine called a potassium-sparing diuretic. Spironolactone and Furosemide have different but complimentary mechanisms and sites of action. Therefore, when given together they produce additive or synergistic diuretic. The Furosemide component inhibits the  $\text{Na}^+/\text{K}^+/2\text{Cl}^-$  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 Furosemide, is reduced.

## Composition

**Frusin® Plus 20:** Each film-coated tablet contains

Furosemide BP 20 mg and Spironolactone BP 50 mg.

**Frusin® Plus 40:** Each film-coated tablet contains

Furosemide BP 40 mg and Spironolactone BP 50 mg.

## Indications

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

1-4 tablets daily (50 to 200 mg of spironolactone and 20 to 80 mg of Furosemide) according to the patient's response. For previously stabilized patients requiring higher dosage of spironolactone and Furosemide (spironolactone 50 to 100 mg and Furosemide 40 to 80 mg).

## Contraindications

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, Furosemide or sulphonamides.

## Side effects

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 hyponatraemia and hyperkalaemia. 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.

## Use in pregnancy and lactation

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 Furosemide may cause foetal abnormalities. Therefore, Furosemide 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. 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. Furosemide is excreted in breast milk and breast-feeding should be discontinued if treatment is essential.

## Precautions

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 interactions

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

## Over dosage

Dehydration, electrolyte depletion and hypotension may be caused by over dosage or accidental ingestion. The drug should be discontinued and appropriate corrective treatment applied: replacement of excessive fluid and electrolyte losses; serum electrolytes, carbon dioxide level and blood pressure should be determined frequently.

## Storage

Store in a cool (Below 25° C temperature) and dry place protected from light.

## Packaging

**Frusin® Plus 20:** Each carton contains 10X3 tablets in blister strips.

**Frusin® Plus 40:** Each carton contains 10X3 tablets in blister strips.

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