TRILIX® SR

Indapamide 1.5 mg

Presentation:
Each sustained-release film-coated tablet contains Indapamide USP 1.5 mg

Uses:
Essential hypertension.

Dosage & Administration:
Oral administration.
One tablet per 24 hours, preferably in the morning, to be swallowed whole with water and not chewed.
At higher doses the antihypertensive action of indapamide is not enhanced but the saluretic effect is increased.

Contraindications:
Hypersensitivity to sulphonamides.
Severe renal failure.
Hepatic encephalopathy or severe impairment of liver function.
Hypokalaemia.

Use in Pregnancy & Lactation:
Pregnancy
As a general rule, the administration of diuretics should be avoided in pregnant women and should never be used to treat physiological oedema of pregnancy. Diuretics can cause foetoplacental ischaemia, with a risk of impaired foetal growth.
Lactation
Breast-feeding is inadvisable (Indapamide is excreted in human milk).

Side Effects:
The majority of adverse effects concerning clinical or laboratory parameters are dose-dependent. Thiazide-related diuretics, including indapamide, may cause:
Blood and the lymphatic system disorders:
Very rare: thrombocytopenia, leucopenia, agranulocytosis, aplastic anaemia, haemolytic anaemia
Nervous system disorders:
Rare: vertigo, fatigue, headache, paresthesia.
Cardiac disorders:
Very rare: arrhythmia, hypotension.
Gastrointestinal disorders:
Rare: nausea, constipation, dry mouth.
Very rare: pancreatitis.
Hepato-biliary disorders:
In case of hepatic insufficiency, there is a possibility of onset of hepatic encephalopathy.
Very rare: abnormal hepatic function.

Warning & Precautions:
Special Warnings
When liver function is impaired, thiazide-related diuretics may cause hepatic encephalopathy. Administration of the diuretic must be stopped immediately if this occurs.
Special precautions for use

Water and electrolyte balance:
Plasma sodium:
This must be measured before starting treatment, then at regular intervals subsequently. Any diuretic treatment may cause hyponatraemia, sometimes with very serious consequences. The fall in plasma sodium may be asymptomatic initially and regular monitoring is therefore essential, and should be even more frequent in the elderly and cirrhotic patients.
Plasma potassium:
Potassium depletion with hypokalaemia is the major risk of thiazide and related diuretics. The risk of onset of hypokalaemia (< 3.4 mmol/l) must be prevented in certain high risk populations, i.e. the elderly, malnourished and/or polymedicated, cirrhotic patients with oedema and ascites, coronary artery disease and cardiac failure patients. In this situation, hypokalaemia increases the cardiac toxicity of digitalis preparations and the risks of arrhythmias.

Drug Interaction:
Combinations that are not recommended

Lithium:
Increased plasma lithium with signs of overdosage, as with a salt-free diet (decreased urinary lithium excretion). However, if the use of diuretics is necessary, careful monitoring of plasma lithium and dose adjustment are required.

Combinations requiring precautions for use

class Ia antiarrhythmics (quinidine, hydroquinidine, disopyramide),

class III antiarrhythmics (amiodarone, sotalol, dofetilide, ibutilide),

some antipsychotics: phenothiazines (chlorpromazine, cyamemazine, levomepromazine, thioridazine, trifluoperazine),

benzamides (amisulpride, sulpiride, sultopride, tiapride),

butyrophenones (droperidol, haloperidol);

others: bepridil, cisapride, diphemanil, erythromycin IV, halofantrine, mizolastine, pentamidine, sparfloxacin, moxifloxacin, vincamine IV.

Metformin:
Increased risk of metformin induced lactic acidosis due to the possibility of functional renal failure associated with diuretics and more particularly with loop diuretics. Do not use metformin when plasma creatinine exceeds 15 mg/l (135 µmol/l) in men and 12 mg/l (110 µmol/l) in women.

Storage :
Store in a cool & dry place, away from light. Keep out of the reach of children.

Commercial Packaging: Trilix SR tablet: Box containing 20's tablets in Blister Pack.

Manufactured by :
Silva
Pharmaceuticals Limited
Maijdee, Noakhali, Bangladesh