Induric®SR (Tablets)

1324
Ref. No.:INS324/06.19

Indapamide

Diuretic

INDURIC® SR 1.5MG TABLETS

PRESENTATION:
Induric® SR 1.5mg Tablets: White to off white circular, biconvex tablet plain on both sides. Each sustained release tablet contains: Indapamide Hemihydrate equivalent to Indapamide 1.5mg.

CLINICAL PHARMACOLOGY:
Indapamide is a sulphonamide derivative with an indole ring, pharmacologically related to thiazide diuretics, which acts by inhibiting the reabsorption of sodium in the cortical dilution segment. It increases the urinary excretion of sodium and chlorides and, to a lesser extent, the excretion of potassium and magnesium, thereby increasing urine output and having an antihypertensive action.
Phase II and III studies using monotherapy have demonstrated an antihypertensive affect lasting 24 hours. This was present at doses where the diuretic effect was of mild intensity.
The antihypertensive activity of indapamide is related to an improvement in arterial compliance and a reduction in arteriolar and total peripheral resistance.
Indapamide reduces left ventricular hypertrophy.
Thiazide and related diuretics have a plateau therapeutic effect beyond a certain dose, while adverse effects continue to increase. The dose should not be increased if treatment is ineffective.
It has also been shown in the short, mid and long term effects in hypertensive patients that indapamide: does not interfere with lipid metabolism: triglycerides, LDL-cholesterol and HDL-cholesterol; does not interfere with carbohydrate metabolism, even in diabetic hypertensive patients.
Pharmacokinetics:
Indapamide is rapidly and completely absorbed from the gastrointestinal tract. Elimination is biphasic with a half life in whole blood of about 14 hours. Indapamide is strongly bound to red blood cells. It is extensively metabolised. About 60 to 70% of the dose has been reported to be excreted in the urine; only about 5 to 7% is excreted unchanged. About 16 to 23% of dose is excreted in the faeces. Indapamide is not removed by haemodialysis but does not accumulate in patients with renal impairment.

USES:
This drug is prescribed for the treatment of essential hypertension in adults.

DOSAGE AND ADMINISTRATION:
Adults: One tablet daily in the morning.
Children and adolescents: Not recommended.

CONTRA-INDICATIONS AND WARNINGS:
Hypersensitivity to sulfonamides; severe renal failure; hepatic encephalopathy or severe hepatic failure; hypokalemia.
Precautions:
Pregnancy; lactation; monitoring of K+ and uric serum levels is recommended especially in subjects with a predisposition or a sensitivity to hypokalemia and in patients with gout. Although no allergic manifestations have been reported during clinical trials, patients with a history of allergy to sulfonamide derivatives should be closely monitored.
Adverse Effects:

Hypecalcemia, Vertigo, hypersensitivity reactions, Torsade de pointes, Vomiting, Maculopopular rashes.

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Overdosage:
Initial measures involve rapid elimination of ingested substance by gastic washout or administration of activated charcoal, followed by restoration of water or electrolyte balance to normal in a specialised centre. If not able to manage, consult your doctor or pharmacist immediately.

Interactions: Diuretic-induced hypokalaemia may enhance the toxicity of digitalis glycosides and may also increase the risk of arrhythmias with drugs that prolong the QT interval, such as astemizole, terfenadine, halofantrine, pimozide, and sotalol. Thiazides may enhance the neuromuscular blocking action of competitive neuromuscular blockers, such as atracurium, probably by their hypokalaemic effect. The potassium-depleting effect of diuretics may be enhanced by corticosteroids, corticotropin, $beta_2$ agonists such as salbutamol, carbenoxolone, amphotericin B, or reboxetine. Diuretics may enhance the effect of other antihypertensives, particularly the first-dose hypotension that occurs with alpha blockers or ACE inhibitors. Orthostatic hypotension associated with diuretics may be enhanced by alcohol, barbiturates, or opioids. The antihypertensive effects of diuretics may be antagonised by drugs that cause fluid retention, such as corticosteroids, NSAIDs, or carbenoxolone; diuretics may enhance the nephrotoxicity of NSAIDs. Thiazides have been reported to diminish the response to pressor amines, such as noradrenaline, but the clinical significance of this effect is uncertain. Thiazides should not usually be used with lithium since the association may lead to toxic blood concentrations of lithium. Other drugs for which increased toxicity has been reported when given with thiazides include allopurinol and tetracyclines. Thiazides may alter the requirements for hypoglycaemics in diabetic patients.
Drug combinations to be avoided; lithium; nonantiarrhythmic drugs causing wave burst arrhythmia such erythromycin, halofantrine, pentamidine, terfenadine and vincamine.

Pregnancy and breastfeeding

Induric® SR should be avoided during pregnancy and breastfeeding.

PHARMACEUTICAL PRECAUTIONS:
Store in a dry place below 30ºC. Protect from light. Keep all medicines out of the reach of children.

LEGAL CATEGORY:
Prescription Only Medicine (POM)

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COSMOS

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