Important Information. Please read carefully.

RINALIX®
INDAPAMIDE

Tablets

Composition
Each tablet contains: Indapamide 2.5 mg

Pharmacology
Indapamide is a diuretic with actions similar to those of the thiazide diuretics. It acts directly on the kidney to increase the excretion of sodium chloride and water; it also increases the excretion of K^+.
Indapamide is rapidly and completely absorbed from the gastro-intestinal tract. A minimum of 70% of a single oral dose is eliminated by the kidneys and an additional 23% by the gastrointestinal tract, probably including the biliary route. The half-life of Indapamide in whole blood is approximately 14 hours. Indapamide is strongly and reversibly bound to red blood cells. Indapamide is not removed by haemodialysis but does not accumulate in patients with impaired renal function.

Indications
Rinalix is indicated for the treatment of essential hypertension, alone or in combination with other antihypertensive drugs.

Dosage and Administration
To be administered orally.
Hypertension: 2.5 mg daily, to be taken in the morning. The action of Indapamide is progressive and the reduction in blood pressure may continue and not reach a maximum until several months after the initiation of therapy. A larger dose than 2.5 mg Indapamide is not recommended as there is no appreciable antihypertensive effect but a diuretic effect may become apparent.

Contraindications
Anuria, stroke, recent cerebrovascular accident, severe hepatic insufficiency, known hypersensitivity to indapamide or to other sulfonamide-derived drugs.

Precautions / Warnings
Hypokalemia, Hyponatremia, and Other Fluid and Electrolyte Imbalances: Periodic determinations of serum electrolytes should be performed at appropriate intervals. Patients should be observed for clinical signs of fluid or electrolyte imbalance, such as hyponatremia, hypochloremic alkalosis, or hypokalemia.
Hyperuricemia and Gout: Serum concentrations of uric acid was reported to increase in patients treated with indapamide, and frank gout may be precipitated in certain patients receiving indapamide. Serum concentrations of uric acid should therefore be monitored periodically during treatment.
Renal Impairment: Indapamide should be used with caution in patients with severe renal disease, as reduced plasma volume may exacerbate or precipitate azotemia. If progressive renal impairment is observed, withholding or discontinuing diuretic therapy should be considered. Renal function tests should be performed periodically during treatment with indapamide.
Impaired Hepatic Function: Indapamide should be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma.
Calcium Excretion: Calcium excretion is decreased by diuretics pharmacologically related to indapamide. Prolonged treatment with drugs pharmacologically related to indapamide may in rare instances be associated with hypercalcemia and hypophosphatemia secondary to physiologic changes in the parathyroid gland; however, the common complications of hyperparathyroidism, such as renal lithiasis, bone resorption, and peptic ulcer, have not been seen. Treatment should be discontinued before tests for parathyroid function are performed. Like the thiazides, indapamide may decrease serum PBI (protein-bound iodine) levels without signs of thyroid disturbance.
Choroidal Effusion, Acute Myopia, and Secondary Angle-Closure Glaucoma: Sulfonamide or sulfonamide derivative drugs can cause an idiosyncratic reaction resulting in choroidal effusion with visual field defect, transient myopia and acute angle-closure glaucoma. Symptoms may include acute onset of decreased visual acuity or ocular pain and typically occur within hours to weeks of drug initiation. Untreated acute angle-closure glaucoma can lead to permanent vision loss. The primary treatment is to discontinue drug intake as rapidly as possible. Prompt medical or surgical treatments may need to be considered if the intraocular pressure remains uncontrolled. Risk factors for developing acute angle-closure glaucoma may include a history of sulfonamide or penicillin allergy.
Use in Elderly: Plasma potassium and urate concentrations should be monitored when indapamide is used in elderly.
Usage in Pregnancy: Reproduction studies have been performed in animals and have revealed no evidence of impaired fertility or harm to the fetus due to indapamide. There are, however, no adequate and well-controlled studies in pregnant women. Moreover, diuretics are known to cross the placental barrier and appear in cord blood. Therefore the drug should be used during pregnancy only if clearly needed. There may be hazards associated with this use such as fetal or neonatal aundice, thrombocytopenia, and possibly other adverse reactions that have occurred in the adult.
Nursing Mothers: It is not known whether this drug is excreted in human milk. Because most drugs are excreted in human milk, if use of this drug is seemed essential, the patient should stop nursing.

Adverse Effects
Most adverse effects have been mild and transient. The more common side effects include hypokalemia, orthostatic hypotension, and allergic reactions including rash and pruritus. There may be slight increase in serum uric acid level.
Eye disorders: Choidal effusion (*frequency not known*), acute angle-closure glaucoma (*frequency not known*), myopia (*frequency not known*)

Drug Interactions
*Lithium: In general, diuretics should not be given concomitantly with lithium because they reduce its renal clearance and add a high risk of lithium toxicity.
*Fenoxedil, lidoflazine, prenylamine and vincamine, non-antiarrhythmic drugs inducing wave burst arrhythmia (hypokalemia or even bradycardia and a preexisting long Q-T interval are predisposing factors).
*Tienilic Acid: Acute renal failure, (intratubular precipitation of urates related to the uricosuric effect of tienilic acid and to the state of dehydration due to other diuretics).
Other Antihypertensives: Indapamide may add to or potentiate the action of other antihypertensive drugs.
Norepinephrine: Indapamide, like the thiazides, may decrease arterial responsiveness to norepinephrine, but this diminution is not sufficient to preclude effectiveness of the pressor agent for therapeutic use.
NSAIDs (systemic route): Acute renal insufficiency in the dehydrated patient (reduction in glomerular filtration due to the inhibition of vasodilator prostaglandins by the NSAIDS). Hydrate the patient and monitor renal function at the start of treatment.
Metformin: Lactic acidosis due to metformin triggered by possible functional renal failure related to the diuretics.
Do not use metformin when blood creatinine levels exceed 15 mg/litre (135 micromoles/litre) in men and 12 mg/litre (110 micromoles/litre) in women.
Iodinated contrast media: In cases of dehydration caused by diuretics, there is an increased risk of acute renal failure, in particular when high doses of iodinated contrast media are used. Rehydration before administration of the iodinated product.
Antiarrhythmics inducing wave burst arrhythmia: sotalol, amiodarone, bepridil and quinidine-type anti-arrhythmic drugs (class Ia),
Wave burst arrhythmia (hypokalemia and even bradycardia and pre-existing long Q-T interval are predisposing factors).
Prevention and, if necessary, correction of the hypokalemia, monitoring of the Q-T interval; do not give antiarrhythmic drugs in cases of wave burst arrhythmia (cardiac pacing).
Other hypokalemia drugs: amphotericin B (IV route), glucocorticoids and mineralocorticoids (systemic route), tetracosactide, stimulant laxatives: increased risk of hypokalemia (additive effect).
Hyperkalemia diuretics (amiloride, canrenone, spironolactone, triamterene).
Rational drug combinations which are useful in certain patients do not exclude the occurence of hypokalemia or hyperkalemia in particular in patients with renal failure and diabetes.
Digitalis glycosides: Hypokalemia potentiates the toxic effects of digitalis glycosides.
*Inadvisable combinations

Symptoms and Treatment of Overdosage
Symptoms of overdosage include nausea, vomiting, weakness, gastrointestinal disorders and disturbances of electrolyte balance. In severe instances, hypotension and depressed respiration may be observed. If this occurs, support of respiration and cardiac circulation should be instituted.
There is no specific antidote. An evacuation of the stomach is recommended by emesis and gastric lavage after which the electrolyte and fluid balance should be evaluated carefully.

Shelf-life
The expiry date is indicated on the packaging.

Description
Pink color, round and deep convex film-coated tablet, 5.5 mm in diameter in packs of 60's. 15's tablets per blister.

Storage
Store at room temperature below 30°C. Protect from light and moisture.

KEEP OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK.

For further information, please consult your pharmacist or physician

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Xepa sp
Manufactured and Marketed by
Xepa-Soul Pattinson (Malaysia) Sdn Bhd
1-5 Cheng Industrial Estate
75250 Melaka, Malaysia.