

INDAPAMIDE

VAZAMIDE SR

ANTIHYPERTENSIVE

xxxxxxx-5343

FORMULATION

Each sustained release tablet contains:

Indapamide.....1.5 mg

PHARMACOKINETICS

Indapamide is rapidly and completely absorbed from the gastro-intestinal 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 extremely 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 the administered dose is excreted haemodialysis but does not accumulate in patients with impaired renal function.

INDICATION

Indapamide is indicated in the management of mild to moderate hypertension and also for oedema, including that associated with heart failure.

DOSAGE AND ADMINISTRATION

One tablet once daily, or as directed by the physician.

WARNING

Electrolyte changes observed with Indapamide become more prominent at doses above 1.5 mg sustained release tablet/day. The daily maximum recommended dose of Indapamide is 1.5 mg administered as one sustained release tablet.

PRECAUTION

Patients receiving indapamide should be monitored for signs and symptoms of fluid or electrolyte imbalance; namely hypotraemia, hypochloreaemia and hypokalaemia. Blood urea nitrogen and uric acid should also be assessed during therapy. The signs of electrolyte imbalance are dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscle fatigue, hypotension, oliguria, gastrointestinal disturbances such as nausea and vomiting, tachycardia, and ECG changes.

CONTRAINDICATION

Indapamide is contraindicated in :

- Individuals who are hypersensitive to Indapamide or other sulphonamide type medications.
- Severe hepatic insufficiency.
- Severe renal failure with creatinine clearance.

ADVERSE EFFECTS

In general, most adverse effects are mild and transient with the most frequently reported being giddiness, diarrhoea, headache, anorexia, gastric irritation, nausea, vomiting, abdominal pain usually occurring within the first month of treatment. Electrolyte imbalances including hypochloreaemic alkalosis, hyponatraemia, hypokalaemia and hyperuricaemia; hypersensitivity reactions which include skin rashes, pulmonary oedema, pneumonitis, cholestatic jaundice, pancreatitis and blood dyscrasias including thrombocytopenia and less frequently granulocytopenia, leucopenia, aplastic anemia and haemolytic anaemia have been reported. Serum potassium should be monitored in patients with a history of gout, who should continue to receive appropriate treatment.

STORAGE

Store at temperatures not exceeding 30°C.

AVAILABILITY

In a box of 100's (Blister pack of 10 tablets).

CAUTION

Foods, Drugs, Devices & Cosmetics Act prohibits dispensing without prescription.



Manufactured by :
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