150mm

Important information. Please read carefully.

Hydrochlorzide-25™
Hydrochlorzide-50™
Tablets

COMPOSITION
Hydrochlorzide-25 Tablet: Each tablet contains Hydrochlorothiazide 25mg.
Hydrochlorzide-50 Tablet: Each tablet contains Hydrochlorothiazide 50mg.

PRODUCT DESCRIPTION
Hydrochlorzide-25 Tablet: Light orange, round, flat beveled edge tablet with breakline and embossed 'XS' on one side, 6.3 mm in diameter.

Hydrochlorzide-50 Tablet: Light orange, round, flat beveled edge tablet with breakline and embossed 'XS' on one side, 7.9 mm in diameter.

The breakline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

PHARMACODYNAMICS
Pharmacotherapeutic group: Diuretics, ATC code: C03AA03
Hydrochlorothiazide is a diuretic which acts by reducing resorption of electrolytes from renal tubules, thereby increasing excretion of sodium and chloride ions and consequently of water. It also reduces carbonic-anhydrase activity, to increase the excretion of bicarbonate, without significant change in urinary pH.

Non-melanoma skin cancer: Based on available data from epidemiological studies, cumulative dose-dependent association between hydrochlorothiazide and NMSC has been observed. One study included a population comprised of 71,533 cases of BCC and of 8,629 cases of SCC matched to 1,430,833 and 172,462 population controls, respectively. High hydrochlorothiazide use (≥50,000 mg cumulative) was associated with an adjusted OR of 1.29 (95% CI: 1.23-1.35) for BCC and 3.98 (95% CI: 3.68-4.31) for SCC. A clear cumulative dose response relationship was observed for both BCC and SCC. Another study showed a possible association between lip cancer (SCC) and exposure to hydrochlorothiazide: 633 cases of lip-cancer were matched with 63,067 population controls, using a risk-set sampling strategy. A cumulative dose response relationship was demonstrated with an adjusted OR 2.1 (95% CI: 1.7-2.6) increasing to OR 3.9 (3.0-4.9) for high use (~25,000 mg) and OR 7.7 (5.7-10.5) for the highest cumulative dose (~100,000 mg).

PHARMACOKINETICS
Hydrochlorothiazide is fairly rapidly absorbed from the gastrointestinal tract. It is reported to have a bioavailability of 65 to 70%. It has been estimated to have a plasma half-life of between about 5 and 15 hours and appears to be preferentially bound to red blood cells. It is excreted mainly unchanged in the urine.

INDICATION
Adjunctive therapy in edema associated with congestive heart failure, hepatic cirrhosis, corticosteroid, and estrogen therapy and in edema of renal origin (i.e. nephrotic syndrome, acute glomerulonephritis, chronic renal disease).

In the management of hypertension, hydrochlorothiazide may be used alone or as an adjunct to other antihypertensive drugs. Since it enhances the action of these agents, their dosage must be reduced to avoid an excessive drop in blood pressure and other adverse effects.

DOSAGE AND ADMINISTRATION
To be administered orally.
Diuresis: the usual initial adult dose is 25 to 200 mg per day; the maintenance dose is 25 to 100 mg per day, depending on patient response. Some patients may respond to intermittent therapy (alternate days or 3 to 5 days per week).

The usual oral dosage for children is 2 mg/kg per day, given in 2 divided doses.

Infants under 6 months of age may require up to 3 mg/kg per day, in 2 divided doses.

Hypertension: Usual adult dose is 25 to 50 mg once or twice daily. Doses above this level may increase effectiveness very little but cause more side effects such as hypokalemia. In hypertension associated with renal failure volume overload more potent diuretics, such as loop diuretics may have to be used. On addition of a thiazide to a regimen of other nondiuretic antihypertension agents, an additive blood pressure lowering effect can be anticipated.

CONTRAINDICATIONS
Anuria, known hypersensitivity to this product or to other sulphonamides derived drugs.

WARNINGS AND PRECAUTIONS
Patients should be carefully monitored for signs of fluid and electrolyte imbalance (hyponatraemia; hypochloraemic alkalosis; hypokalaemia and hypomagnesaemia).

Use with caution in impaired renal or hepatic function and diabetes mellitus. It may precipitate attacks of gout in susceptible patients. The possibility of sensitivity reaction should be considered in patients with or without a history of allergy or bronchial asthma.

The possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

An increased risk of non-melanoma skin cancer (NMSC) [basal cell carcinoma (BCC) and squamous cell carcinoma (SCC)] with increasing cumulative dose of hydrochlorothiazide exposure has been observed in two epidemiological studies based on the Danish National Cancer Registry. Photosensitizing actions of hydrochlorothiazide could act as a possible mechanism for NMSC.

Patients taking hydrochlorothiazide should be informed of the risk of NMSC and advised to regularly check their skin for any new lesions and promptly report any suspicious skin lesions. Possible preventive measures such as limited exposure to sunlight and UV rays and, in case of exposure, adequate protection should be advised to the patients to minimize the risk of skin cancer. Suspicious skin lesions should be promptly examined potentially including histological examinations of biopsies. The use of hydrochlorothiazide may also need to be reconsidered in patients who have experienced previous NMSC.

Acute Respiratory Toxicity
Very rare severe cases of acute respiratory toxicity, including acute respiratory distress syndrome (ARDS) have been reported after taking hydrochlorothiazide. Pulmonary oedema typically develops within minutes to hours after hydrochlorothiazide intake. At the onset, symptoms include dyspnoea, fever, pulmonary deterioration, and hypotension. If diagnosis of ARDS is suspected, hydrochlorothiazide should be withdrawn and appropriate treatment given. Hydrochlorothiazide should not be administered to patients who previously experienced ARDS following hydrochlorothiazide intake.

240mm

PREGNANCY AND LACTATION
Use in pregnancy: Use of Thiazides when pregnancy is present or suspected requires that the benefits of the drug be weighed against possible hazards to the foetus.

Use in breast-feeding mothers: Thiazides appear in breast milk. If use of the drug is deemed essential, the patients should stop breast feeding.

DRUG INTERACTIONS
Hydrochlorothiazide when given concurrently with alcohol, barbiturates or narcotics may cause potentiation of orthostatic hypotension. Dosage adjustment may be required if antidiabetic drug (oral agents and insulin) is given concurrently with thiazide diuretics. Potentiation may occur with other antihypertensive drugs. With corticosteroids and ACTH, intensified electrolyte depletion, particularly hypokalemia may occur. Lithium should generally not be given with diuretics.

SIDE EFFECTS
Side effects of the gastrointestinal system are anorexia, gastric irritation, nausea, vomiting, cramps, diarrhoea, constipation, jaundice, pancreatitis, and salivary gland inflammation.

Effects on central nervous system include dizziness, vertigo, paraesthesiae, headache and yellow vision.

Other side effects include hypotension, impotence, hyperglycemia, glycosuria, hyperuricaemia, electrolyte imbalance, leucopenia, agranulocytosis, thrombocytopenia, aplastic and haemolytic anaemia, hypersensitivity, purpura, photosensitivity, rash and urticaria.

Neoplasms benign, malignant, and unspecified (incl. cysts and polyps)
Frequency 'not known': Non-melanoma skin cancer (Basal cell carcinoma and Squamous cell carcinoma).

Non-melanoma skin cancer: Based on available data from epidemiological studies, cumulative dose-dependent association between hydrochlorothiazide and non-melanoma skin cancer has been observed.

Eye disorders
Frequency 'not known': Choroidal effusion, acute myopia, acute angle-closure glaucoma.

Respiratory, thoracic, and mediastinal disorders
Frequency 'very rare': Acute respiratory distress syndrome (ARDS)

OVERDOSAGE AND TREATMENT
Symptoms
Overdosage may lead to excessive diuresis with electrolyte depletion (hypokalemia, hypochloremia, hyponatremia) and dehydration. Signs are dry mouth, thirst, weakness, lethargy, drowsiness, restlessness muscle pains or cramps, muscular fatigue, hypotension, oliguria tachycardia, gastrointestinal disturbances, mental confusion, delirium, convulsions, shock, coma. If digitalis has also been administered, hypokalemia may accentuate myocardial abnormalities (e.g., cardiac arrhythmias). Hydrochlorothiazide may precipitate hepatic coma in cirrhotics, potentiate other antihypertensive agents, and decrease responsiveness to norepinephrine.

Treatment
There is no specific antidote. If ingestion is recent, gastric lavage or emesis may reduce absorption; when ingestion has been earlier, infusions may be helpful to promote urinary excretion. Otherwise, management includes symptomatic treatment with special attention to cardiac rate and output, blood volume, electrolyte balance, dehydration, paralytic ileus, urinary function, hepatic coma, and cerebral activity. Administration of sympathomimetic drugs (e.g., dopamine) may be indicated. Administer oxygen or artificial respiration for respiratory impairment.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE
None known. When driving vehicles or operating machines, it should be taken into account that occasionally dizziness or weariness may occur.

SHELF LIFE
5 years from the date of manufacture

PRESENTATION
Hydrochlorzide-25 Tablet: Blister pack of 30's and 100's
Hydrochlorzide-50 Tablet: Blister pack of 30's and 100's

STORAGE
Store below 30°C.

KEEP OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK

For further information, please consult your pharmacist or physician.

NAME AND ADDRESS OF MANUFACTURERS
Packed and released by:
GoodScience Sdn Bhd
No. 7, Jalan KPK 4/3, Kawasan Perindustrian Kundang, Kundang Jaya, 48020 Rawang, Selangor, Malaysia.

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

PRODUCT REGISTRATION HOLDER
GoodScience Sdn Bhd
No. 7, Jalan KPK 4/3, Kawasan Perindustrian Kundang, Kundang Jaya, 48020 Rawang, Selangor, Malaysia.

Revision Date: 07-June-2024

PM-00137/28-05-24/REV02