PATIENT INFORMATION LEAFLET
HYDROCHLOROTHIAZIDE TABLETS USP 25 MG
[Hydrochlorothiazide USP]

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your physician, health care provider or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist.

WHAT IS IN THIS LEAFLET:

1. WHAT HYDROCHLOROTHIAZIDE TABLETS USP 25 MG IS AND WHAT IT IS USED FOR

It contains the active substance hydrochlorothiazide. This belongs to a group of medicines called' Thiazide diuretic'. Therapeutically as antihypertensive. It has pharmacologically action, increases sodium and water excretion by inhibiting sodium reabsorption in distal tubules; promotes excretion of chloride, potassium, magnesium, and bicarbonate. Also may produce arteriolar dilation, reducing blood pressure. It is indicated in follow treatments of adjunctive therapy in edema associated with congestive heart failure, hepatic cirrhosis, and corticosteroid and estrogen therapy. It has been also found useful in edema due to various forms of renal dysfunction such as nephrotic syndrome, acute glomerulonephritis, and chronic renal failure. It is indicated in the management of hypertension either as the sole therapeutic agent or to enhance the effectiveness of other antihypertensive drugs in the more severe forms of hypertension.

2. BEFORE YOU USE HYDROCHLOROTHIAZIDE TABLETS USP 25 MG

Do not use hydrochlorothiazide tablets USP 25 mg. If you are allergic to hydrochlorothiazide or any of the other ingredients or to other sulfonamide-derived drugs or anuria.

Warnings and precautions: It should be administered with caution to sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma.

Hypokalemia: Hypokalemia may develop, especially with brisk diuresis, when severe cirrhosis's present or after prolonged therapy. Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Hypokalemia may cause cardiac arrhythmia and may also sensitize or exaggerate the response of the heart to the toxic effects of digitalis (e.g., increased ventricular irritability). Hypokalemia may be avoided or treated by use of potassium sparing diuretics or potassium supplements such as foods with high potassium content.

Hyponatremia: Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction, rather than administration of salt, except in rare instances when the hyponatremia is life threatening. In actual salt depletion, appropriate replacement is the therapy of choice. **Hyperuricemia:** Hyperuricemia may occur or acute gout may be precipitated in certain patient's receiving thiazides. **Hypomagnesemia:** Thiazides have been shown to increase the urinary excretion of magnesium. Hyperglycemia: Hyperglycemia may occur with thiazide diuretics. Thus latent diabetes mellitus may become manifest during thiazide therapy. The antihypertensive effects of the drug may be enhanced in the post sympathectomy patient.

Hypercalcemia: Thiazides may decrease urinary calcium excretion.Thiazides may cause intermittent and slight elevation of serum calcium in the absence of known disorders of calcium metabolism.

Using other medicines:

Please tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines. Tell your doctor if you are taking any of the following medicines: Alcohol, Barbiturates, or Narcotics: Potentiation of orthostatic hypotension may occur. Anti-diabetic drugs (Oral agents and Insulin): Dosage adjustment of the anti-diabetic drugs may be required. Other Anti-hypertensive Drugs: Additive effect or potentiation. Cholestyramine and Colestipol Resins: Absorption of hydrochlorothiazide is impaired in the presence of anionic exchange resins. Single doses of either cholestyramine or cotestipol resins bind the hydrochlorothiazide and reduce its absorption from the gastrointestinal tract by up to 85% and 43%, respectively. Corticosteroids, ACTH: Intensified electrolyte depletion, particularly hypokalemia. Skeletal Muscle Relaxants, non-depolarizing (e.g. tubocurarine): Possible increased responsiveness to the muscle relaxant. Lithium: Generally should not be given with diuretics. Diuretic agents reduce the renal clearance of lithium and add a high risk of lithium toxicity. Non-Steroidal Anti-Inflammatory Drugs: Non-steroidal anti-inflammatory agent can reduce the diuretic, natriuretic and anti-hypertensive effects of loop, potassium-sparing and thiazide diuretics. If you have any further questions about this you should speak to your doctor.

Taking Hydrochlorothiazide Tablets USP 25 mg with food and drink: You can take your tablets with or without food. Patients should avoid to intake alcohol with treatment increased hypotension. Sun exposure: increased risk of photosensitivity.

Pregnancy and Lactation: Pregnancy: There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. **Lactation:** Thiazides are excreted in breast milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue hydrochlorothiazide, taking into account the importance of the drug to the mother. **Driving and using machines:** Caution patient to avoid driving and other hazardous activities until he knows how drug affects concentration and alertness.

3. HOW TO USE HYDROCHLOROTHIAZIDE TABLETS USP 25 MG

Always use hydrochlorothiazide tablets USP 25 mg exactly as your physician or health care provider has told you. It can be taken administered orally daily as a single or divided dose with or without meals or as directed by physician. **Method of administration:** Oral, The tablets should be swallowed whole with or without food. The tablets should not be chewed or crushed. For patients who have difficulty in swallowing, the tablets can also be dispersed in half a glass of non-carbonated water. Therapy should be individualized according to patient response. Use the smallest dosage necessary to achieve the required response.

Adults: For Edema: The usual adult dosage is 25 mg to 100 mg daily as a single or divided dose. Many patients with edema respond to intermittent therapy i.e., administration on alternate days or on 3 to 5 days each week. With an intermittent schedule, excessive response and the resulting undesirable electrolyte imbalance are less likely to occur.

For Control of Hypertension: The usual initial dose in adults is 25 mg daily given as a single dose. The dose may be increased to 50 mg daily, given as a single or two divided doses. Doses above 50 mg are often associated with marked reductions in serum potassium. Patients usually do not require doses in excess of 50 mg of hydrochlorothiazide daily when used concomitantly with other antihypertensive agents.

Infants and Children: For Diuresis and for Control of Hypertension: The usual pediatrics dosage is 1 to 2 mg/kg per day in single or two divided doses, not to exceed 37.5 mg per day in infants up to 2 years of age or 100 mg per day in children 2 to 12 years of age. In infants less than 6 months of age, doses up to 3 mg/kg per day in two divided doses may be required.

Renal impairment: It should be used with caution in patients with renal impairment, the thiazides may precipitate azotemia. Cumulative effects of the drug may develop in patients with impaired renal function. **Hepatic impairment:** It should be used with caution in patients with hepatic impairment function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma.

If you more hydrochlorothiazide tablets USP 25 mg than you should: Do not use more than the recommended dose. If taking more than the recommended dose may cause electrolyte depletion (hypokalemia, hypochloremia, hyponatremia) and dehydration resulting from excessive diuresis. If digitalis has also been administered, hypokalemia may accentuate cardiac arrhythmias. The symptomatic and supportive measures should be employed. Emesis should be induced or gastric lavage performed. Correct dehydration, electrolyte imbalance, hepatic coma and hypotension by established procedures. If required, give oxygen or artificial respiration for respiratory impairment. The degree to which hydrochlorothiazide is removed by hemodialysis has not been established. **If you forget to hydrochlorothiazide tablets USP 25 mg:** If you forget to take a dose, Do not take a double dose (two doses at the same time) to make up for a forgotten dose. If you have any further questions on the use of this medicine, ask your doctor or pharmacist. If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with hydrochlorothiazide tablets USP 25 mg.

4. POSSIBLE SIDE EFFECTS

Like all medicines can cause side effects, although not everybody gets them. *Cardiovascular:* Hypotension including orthostatic hypotension (may be aggravated by alcohol, barbiturates, narcotics or antihypertensive drugs). *Digestive:* Pancreatitis, jaundice (intrahepatic cholestatic jaundice), diarrhea, vomiting, cramping, constipation, gastric irritation, nausea, anorexia. *Hematologic:* A plastic anemia, agranulocytosis, leukopenia, hemolytic anemia, thrombocytopenia. *Hypersensitivity:* Anaphylactic reactions, necrotizing angiitis (vasculitis and cutaneous vasculitis), respiratory distress including pneumonitis and pulmonary edema, photosensitivity, fever, urticaria, rash, purpura. *Metabolic:* Electrolyte imbalance, hyperglycemia, glycosuria, hyperuricemia. *Musculoskeletal:* Muscle spasm. *Nervous System/Psychiatric:* Vertigo, paresthesias, dizziness, headache, restlessness. *Renal:* Renal failure, renal dysfunction, interstitial nephritis. *Skin:* Erythema multiforme including *Stevens-Johnson syndrome*, exfoliative dennatitis including toxic epidennal necrolysis, alopecra. *Special Senses:* Transient blurred vision, xanthopsia. *Urogenital:* Impotence. If any of above the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

5. HOW TO STORE HYDROCHLOROTHIAZIDE TABLETS USP 25 MG

Keep this medicine out of the sight and reach of children. Store below 30°C. Protect from light. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

6. FURTHER INFORMATION

It contain active substances as hydrochlorothiazide USP. Each uncoated tablet contains: hydrochlorothiazide USP 25 mg. **Excipients:** Microcrystalline Cellulose (PH 101) BP, Lactose

Monohydrate BP, Maize Starch BP, Sodium Starch Glycolate (Type-A) BP, Colloidal Anhydrous Silica Aerosil BP, Magnesium Stearate BP, Purified water. **Size:** White to off-white coloured, round shaped, flat, uncoated tablets, break line on one side and plain on other side. Such 10 Tablets are packed in a Alu-PVC blister pack. Such 10 Alu-PVC blisters are packed in printed carton with Packing Insert (10 x10).

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