Summary of Product Characteristics

Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Name of the Medicinal Product

Hydrochlorothiazide Tablets BP 25 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains

Hydrochlorothiazide BP 25 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablets

White to off white round flat uncoated tablets with beveled edges and having score line on one side

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

- Hydrochlorothiazide is a diuretic which reduces the reabsorption of electrolytes from the renal tubules.
- Used to treat hypertensive disease and to manage the oedema due to mild-to-moderate congestive heart failure. Oedema due to chronic hepatic or renal disease may also respond favourably
- It may also be used in patients with diabetes insipidus, due to a paradoxical effect.
- May be used in the treatment of hypercalciuria in patients who have recurrent urinary calculi composed of calcium salts
- The use of hydrochlorothiazide has been indicated for the oedema of the premenstrual tension, if there is evidence of fluid retention.

4.2 Posology and Method of administration

Adults

Hypertension

25 to 50 mg daily. Doses of up to 200 mg have been recommended but are rarely necessary.

Oedema

50 to 100 mg daily (initial dose), reduced to a dose of 25 to 50 mg daily or intermittently. 200 mg daily have been recommended.

Renal disorders

50 mg twice daily appeared to be effective in preventing the formation of calcium stones in the urinary tract

Diabetes insipidus

50 mg twice a day.

Premenstrual tension

50 to 100 mg daily.

Children

2.5 mg/kg body-weight daily in two divided doses.

Infants under 6 months may need doses of up to 3.5 mg/kg body-weight daily

Oral: route of administration

4.3 Contraindications

- Contraindicated with allergy to nystatin or components used in preparation.
- Use cautiously with pregnancy, lactation.
- Use for systemic mycoses.

4.4 Special warnings and precautions for use

Hydrochlorothiazide should be used with caution in patients with diabetes, kidney or liver disease or any drug allergy. Caution must be observed when eating large amounts of food high in potassium such as bananas, baked potatoes, raisins, cooked spinach and other foods. Alcoholic beverages may increase the effects of this drug, causing dizziness or lightheadedness, so limit alcohol intake. It should be used with caution while engaging in activities requiring alertness. This drug changes fluid balance, cause dizziness, if change from a lying to a standing position too rapidly, avoid this by sitting up a few minutes before rising. It should be used with caution during pregnancy or lactation.

4.5 Interaction with other medicinal products and other forms of interact.

ACE Inhibitors: Thiazide Diuretics may enhance the hypotensive effect of ACE Inhibitors. Specifically, postural hypotension which can accompany ACE Inhibitor initiation. Thiazide Diuretics may enhance the nephrotoxic effect of ACE Inhibitors.

Allopurinol: Thiazide Diuretics may enhance the potential for allergic or hypersensitivity reactions to Allopurinol. Thiazide Diuretics may increase the serum concentration of Allopurinol. Specifically, Thiazide Diuretics may increase the concentration of Oxypurinolol, an active metabolite of Allopurinol

Bile Acid Sequestrants: May decrease the absorption of Thiazide Diuretics. The diuretic response is likewise decreased.

Calcitriol: Thiazide Diuretics may enhance the hypercalcemic effect of Calcitriol.

Calcium Salts: Thiazide Diuretics may decrease the excretion of Calcium Salts. Continued concomitant use can also result in metabolic alkalosis.

Corticosteroids (Orally Inhaled): May enhance the hypokalemic effect of Thiazide Diuretics.

Corticosteroids (Systemic): May enhance the hypokalemic effect of Thiazide Diuretics.

Dofetilide: Thiazide Diuretics may enhance the QTc-prolonging effect of Dofetilide. Thiazide Diuretics may increase the serum concentration of Dofetilide.

Lithium: Thiazide Diuretics may decrease the excretion of Lithium.

4.6 Fertility, Pregnancy and Lactation

Pregnancy

Although there are no adequate and well-controlled studies using hydrochlorothiazide in pregnancy, thiazide diuretics may cause an increased risk of congenital defects. Hypoglycemia, hypokalemia, hyponatremia, jaundice, and thrombocytopenia are also reported as possible complications to the fetus or newborn.

Lactation

Enters breast milk/use caution

4.7 Effects on ability to drive and use machines

None reported.

4.8 Undesirable effects

Common side effects may include dizziness, fatigue, frequent urination, dry mouth, anxiety, muscle cramps, nervousness, nausea, vomiting, increase in blood sugar and uric acid levels.

Rare side effects may include allergic reactions, upset stomach, appetite loss, constipation, cough, depression, diarrhea, drowsiness, hives, impotence, indigestion, light-headedness, liver disorders, rash, hypersensitivity to light, sore throat, vertigo, and weight

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

Symptoms

The most common signs and symptoms observed are those caused by electrolyte depletion (hypokalemia, hypochloremia, hyponatremia) and dehydration resulting from excessive diuresis.

Treatment

No specific information is available on the treatment of overdosage with Hydrochlorthiazide

5.0 Pharmacological Properties

5.1 Pharmacodynamic Properties

Hydrochlorothiazide acts directly on the kidney, increasing the excretion of sodium chloride and potassium and consequently water, mainly in the distal tubule.

5.2 Pharmacokinetic properties

Absorption

Hydrochlorothiazide is variably but fairly rapidly absorbed from the gastrointestinal tract.

Bio-availability

Hydrochlorothiazide after oral administration is approximately 60 to 80 per cent. Peak plasma level occurs after 1 to 2 hours

Distribution

Hydrochlorothiazide is widely distributed in body tissue and its volume of distribution following oral administration corresponds to 0.83 L/Kg. Protein binding in the plasma is estimated at 58%

Biological half-life

A plasma half-life of about 9.5 hours has been estimated.

The red blood cells half-life is 2.7 to 7 hours

Metabolism

Hydrochlorothiazide is not modified by organic biochemical processes.

Elimination

Elimination of hydrochlorothiazide is mainly due to renal clearance that occurs in about 320 mg/min It is excreted unchanged in the urine. Hydrochlorothiazide crosses the placental barrier and appears in breast milk.

Total systemic clearance of drug from the plasma is 4.9 mL/min/kg , decreasing in patients with uremia or congestive heart failure.

5.3 Preclinical safety data

None stated.

6.0 Pharmaceutical particulars

6.1 List of excipients

Lactose, Maize Starch, Microcrystalline Cellulose, Purified Water, Purified Talc, Magnesium Stearate, Colloidal Anhydrous Silica, Sodium Starch Glycolate (Type A), Croscarmellose Sodium.

6.2 Incompatibilities

None reported

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at temperature not exceeding 30°C in a dry place. Protect from light.

6.5 Nature and contents of container

10 Tablets packed in Printed Blister Aluminium Foil and Clear PVC Film and such 10 blisters packed in a unit carton along with package insert.

6.6 Special precautions for disposal and other handling

None reported

7. Marketing Authorisation Holder

MEDICAMEN BIOTECH LIMITED

SP-1192 A & B, Phase-IV,
Industrial Area, Bhiwadi-301019,
Distt Alwar, Rajasthan India

8. Number(s) in the national register of finished pharmaceutical products

Certificate No: 07971/08484/REN/2022

9. Date of first authorisation/renewal of the authorisation

Oct 21, 2022

10. Date of revision of the text

July 2023