Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

Brand Name : **AGOTHIAZIDE TABLETS** **Generic Name** : Hydrochlorothiazide Tablets BP 50 mg		2021
Module 1 **1.5**	Administrative Information and Product Information Product Information	**Confidential**

1.5 PRODUCT INFORMATION

1.5.1 Prescribing information (Summary of products characteristics)

SUMMARY PRODUCT CHARACTERISTICS

1. Name of drug product:

AGOTHIAZIDE TABLETS (Hydrochlorothiazide Tablets BP 50 mg)

2. Qualitative and Quantitative Composition:

Each uncoated tablet contains: Hydrochlorothiazide BP 50 mg

3. Pharmaceutical form:

White, circular, biconvex uncoated tablets.

4. Clinical particulars:

4.1 Therapeutic Indications:

Hydrochlorothiazide is a thiazide diuretic (water pill) that helps prevent your body from absorbing too much salt, which can cause fluid retention.

Hydrochlorothiazide is used to treat high blood pressure (hypertension).

Hydrochlorothiazide is also used to treat fluid retention (edema) in people with congestive heart failure, cirrhosis of the liver, or kidney disorders, or edema caused by taking steroids or estrogen.

4.2 Posology and Method of Administration:

Usual Adult Dose for Edema:

Usual dose: 25 mg to 100 mg orally once or twice daily

Comments:
-Some patients respond to intermittent therapy, (i.e., administration on alternate days or on 3 to 5 days each week). Excessive response and

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undesirable electrolyte imbalance are less likely to occur with intermittent dosing.

Usual Adult Dose for Hypertension:

Initial dose: 25 mg orally once daily
Maintenance dose: May increase to 50 mg orally daily, as a single or 2 divided doses

Comments:
-Patients usually do not require doses in excess of 50 mg daily when used concomitantly with other antihypertensive agents.

Usual Adult Dose for Nephrocalcinosis:

Initial: 25 mg orally once daily
Maintenance dose: May increase to 50 mg twice daily

Usual Adult Dose for Osteoporosis:

Initial: 25 mg orally once daily
Maintenance dose: May increase to 50 mg daily

Usual Adult Dose for Diabetes Insipidus:

Initial: 50 mg orally once daily
Maintenance dose: May increase to 100 mg orally daily

Usual Pediatric Dose for Edema:

Less than 6 months: Up to 3 mg/kg/day (up to 1.5 mg/pound) orally in 2 divided doses

Less than 2 years: 1 to 2 mg/kg/day (0.5 to 1 mg/pound) orally daily as a single dose or in 2 divided doses
Maximum dose 37.5 mg per day

2 to 12 years: 1 to 2 mg/kg/day (0.5 to 1 mg/pound) orally daily as a single dose or in 2 divided doses
Maximum dose 100 mg per day

Usual Pediatric Dose for Hypertension:

Less than 6 months: Up to 3 mg/kg/day (up to 1.5 mg/pound) orally in 2 divided doses

Less than 2 years: 1 to 2 mg/kg/day (0.5 to 1 mg/pound) orally daily as a single dose or in 2 divided doses
Maximum dose 37.5 mg per day

2 to 12 years: 1 to 2 mg/kg/day (0.5 to 1 mg/pound) orally daily as a single dose or in 2 divided doses
Maximum dose 100 mg per day

Method of administration: Oral.

4.3 Contraindications:

Get emergency medical help if you have **signs of an allergic reaction to hydrochlorothiazide** (hives, difficult breathing, swelling in your face or throat) **or a severe skin reaction** (fever, sore throat, burning eyes, skin pain, red or purple skin rash with blistering and peeling).

Call your doctor at once if you have:

- a light-headed feeling;
- eye pain, vision problems;
- jaundice (yellowing of the skin or eyes);
- pale skin, easy bruising, unusual bleeding (nose, mouth, vagina, or rectum);
- shortness of breath, wheezing, cough with foamy mucus, chest pain;
- **dehydration symptoms** - feeling very thirsty or hot, being unable to urinate, heavy sweating, or hot and dry skin; or
- **signs of an electrolyte imbalance** - increased thirst or urination, confusion, vomiting, constipation, muscle pain, leg cramps, bone pain, lack of energy, irregular heartbeats, tingly feeling.

Common hydrochlorothiazide side effects may include:

- weakness;
- feeling like you might pass out;
- severe pain in your upper stomach spreading to your back, nausea and vomiting;
- fever, chills, tiredness, mouth sores, skin sores, easy bruising, unusual bleeding, pale skin, cold hands and feet, feeling light-headed or short of breath; or
- electrolyte imbalance.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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5. Pharmacological properties:

5.1 Pharmacokinetic Properties:

Hydrochlorothiazide is indicated alone or in combination for the management of edema associated with congestive heart failure, hepatic cirrhosis, nephrotic syndrome, acute glomerulonephritis, chronic renal failure, and corticosteroid and estrogen therapy. Hydrochlorothiazide is also indicated alone or in combination for the management of hypertension.

5.2 Pharmacodynemic Properties:

Hydrochlorothiazide prevents the reabsorption of sodium and water from the distal convoluted tubule, allowing for the increased elimination of water in the urine. Hydrochlorothiazide has a wide therapeutic window as dosing is individualized and can range from 25-100mg. Hydrochlorothiazide should be used with caution in patients with reduced kidney or liver function.

Mechanism of action

Hydrochlorothiazide is transported from the circulation into epithelial cells of the distal convoluted tubule by the organic anion transporters OAT1, OAT3, and OAT4. From these cells, hydrochlorothiazide is transported to the lumen of the tubule by multidrug resistance associated protein 4 (MRP4).

Normally, sodium is reabsorbed into epithelial cells of the distal convoluted tubule and pumped into the basolateral interstitium by a sodium-potassium ATPase, creating a concentration gradient between the epithelial cell and the distal convoluted tubule that promotes the reabsorption of water.

Hydrochlorothiazide acts on the proximal region of the distal convoluted tubule, inhibiting reabsorption by the sodium-chloride symporter, also known as Solute Carrier Family 12 Member 3 (SLC12A3). Inhibition of SLC12A3 reduces the magnitude of the concentration gradient between the epithelial cell and distal convoluted tubule, reducing the reabsorption of water.

Absorption

An oral dose of hydrochlorothiazide is 65-75% bioavailable, with a T_{max} of 1-5 hours, and a C_{max} of 70-490ng/mL following doses of 12.5-100mg. When taken with a meal, bioavailability is 10% lower, C_{max} is 20% lower, and T_{max} increases from 1.6 to 2.9 hours.

Volume of distribution

The volume of distribution varies widely from one study to another with values of 0.83-4.19L/kg.[8]

Protein binding

Hydrochlorothiazide is 40-68% protein bound in plasma. Hydrochlorothiazide has been shown to bind to human serum albumin. **Metabolism**

Hydrochlorothiazide is not metabolized.

Route of elimination

Hydrochlorothiazide is eliminated in the urine as unchanged hydrochlorothiazide.

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6. Pharmaceutical particulars:

6.1 List of Excipients:

Lactose	BP
Di Basic Calcium Phosphate	BP
Maize starch	BP
Methyl Paraben sodium	BP
Propyl Paraben sodium	BP
Purified talc	BP
Magnesium stearate	BP
Colloidal silicon dioxide	BP
Cross Carmellose Sodium	BP
Sodium Starch Glycolate	BP

6.2 Incompatibilities:
None Reported

6.3 Shelf-Life:
36 months from the date of manufacture.

6.4 Special Precautions for Storage:
Store in a cool, dry and dark place. Protect from light.

6.5 Nature and Contents of Container:
1000 tablets packed in one Jar.

6.6 Special precautions for disposal:
None reported.

7. Registrant:
AGOG PHARMA LTD.
Plot No. 33, Sector II,
The Vasai Taluka Industrial
Co-Op. Estate Ltd., Gauraipada,
Vasai (E), Dist. Thane, India.

8. Manufacturer:
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Vasai (E), Dist. Thane,
India.

9. Date of revision of the text :