Hydrochlorothiazide Tablets USP 12.5 mg, 25 mg and 50 mg

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: Hydrochlorothiazide Tablets USP 12.5 mg, 25 mg and 50 mg

Marketing Authorisation Holder
Accord Healthcare, Inc.,
1009 Slater Road,
Suite 210-B,
Durham, NC 27703, USA.
Telephone: 1-919-941-7878
Fax: 1-919-941-7881

Manufacturer
Intas Pharmaceuticals Ltd.
Plot No. 457, 458
Village-Matoda,
Bavla Road, Ta. Sanand,
Dist. Ahmedabad-382 210,
Gujarat, India

US Emergency Phone: Call CHEMTREC Day or Night: 1-800-424-9300

SECTION 2 – COMPOSITION, INFORMATION ON INGREDIENTS

Active: Hydrochlorothiazide USP

Inactive: Dibasic calcium phosphate dihydrate, FD & C yellow no. 6, lactose monohydrate, magnesium stearate, pregelatinized starch (starch 1500) and sodium starch glycolate.

SECTION 3 - HAZARDS IDENTIFICATION

Adverse Effects: Adverse effects of thiazide diuretics are usually dose-related and may include increased urination, confusion, convulsions, muscle cramps or pain, dry mouth, increased thirst, irregular heartbeat, mood or mental changes, nausea, vomiting, unusual tiredness or weakness, weak pulse, loss of appetite, decreased sexual ability, diarrhea, dizziness, upset stomach, fever, increased sensitivity of skin to sunlight, and skin eruptions and rash. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: Overdose effects may include adverse effects above, leading to difficulty breathing and coma.

Acute: Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

Chronic: Possible hypersensitization.
Medical Conditions Aggravated by Exposure: Hypersensitivity to material, anuria, hyperuricemia or gout, impaired liver (severe) or kidney function, hypercalcemia, lupus erythematosus, porphyria, diabetes mellitus, and Addison's disease.

Cross Sensitivity: Persons sensitive to other sulfonamide-type medications, bumetanide, furosemide, or carbonic anhydrase inhibitors may be sensitive to this material also.

Target Organs: Kidneys, heart, central nervous system.

SECTION 4 - EMERGENCY & FIRST AID MEASURES

Inhalation: May cause irritation. Remove to fresh air.

Eye: Causes mild irritation. Avoid contact. Flush with copious quantities of tepid water for at least 15 minutes.

Skin: May cause irritation. Flush with copious quantities of water.

Ingestion: May cause irritation and slightly bitter taste. Flush out mouth with water. This material is readily absorbed from the gastrointestinal tract. Its onset of action is within 2 hours; duration of action is 6 to 12 hours.

General First Aid Procedures: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Note to Physicians

Overdose Treatment: Treatment of thiazide diuretic overdose should be symptomatic and supportive and may include the following:
1. Administer activated charcoal as a slurry.
2. Cathartics may potentiate fluid and electrolyte disturbances and should be AVOIDED.
3. For dysrhythmias, first correct electrolyte imbalance. If dysrhythmia persists despite correction, treat with standard advanced cardiac life support protocols.

SECTION 5 - FIRE FIGHTING MEASURES

Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.
**Firefighting Procedures:** As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

**Fire and Explosion Hazards:** This material is assumed to be combustible. As with all dry powders, it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

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**SECTION 6 - ACCIDENTAL RELEASE MEASURES**

**Spill Response:** Wear approved respiratory protection, chemically compatible gloves, and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labeled containers for disposal. Wash spill site.

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**SECTION 7 - HANDLING AND STORAGE**

**General Handling:** Minimize dust generation and accumulation. If tablets are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment. Wash hands and any exposed skin after removal of personal protective equipment. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases.

Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems, or other equivalent controls. Releases to the environment should be avoided.

**Storage:** Store at 20°C to 25°C (68°F to 77°F).

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**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Engineering Controls:** Engineering controls such as exhaust ventilation are recommended.

**Respiratory Protection:** Use a NIOSH approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

**Gloves:** Chemically compatible

**Eye Protection:** Safety glasses or goggles
Protective Clothing: Protect exposed skin.

Exposure Limits: Industry: 500 micrograms/m³

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Description of Tablets:
The 12.5 mg tablets are light orange to peach colored, round, biconvex tablets debossed with H on one side and 1 on another side.
The 25 mg tablets are light orange to peach colored, round, flat tablets with beveled edges and debossed with H & 2 on either side of break line and another side is plain.
The 50 mg tablets are light orange to peach colored, round, flat tablets with beveled edges and debossed with H & 3 on either side of break line and another side is plain.

Solubility: Slightly soluble in water, freely soluble in sodium hydroxide solution, in n-butyl amine and dimethyl formamide, sparingly soluble in methanol, insoluble in ether, in chloroform and in dilute mineral acids.

SECTION 10 - STABILITY AND REACTIVITY

Stability: The product is stable

Polymerization: No

Conditions to Avoid: Avoid exposure to moisture.

Incompatibilities: Not found

Decomposition Products: When heated to decomposition material emits very toxic fumes of SOx, NOx, and Cl-. Emits toxic fumes under fire conditions.

SECTION 11 - TOXICOLOGY INFORMATION

Oral Rat: LD₅₀: 2750 mg/kg

Oral Mouse: LD₅₀: 1175 mg/kg

Listed as a Carcinogen by: NTP: No IARC: No OSHA: No
MATERIAL SAFETY DATA SHEET

Other Carcinogenicity Data: This material is not classifiable as to its carcinogenicity in humans. Two-year feeding studies in mice and rats revealed no evidence of carcinogenic potential of hydrochlorothiazide in female mice at doses up to 600 mg/kg/day or in male and female rats at doses up to 100 mg/kg/day. There was equivocal evidence for hepatocarcinogenicity (increased incidence of hepatocellular neoplasms) in male mice.

Mutagenicity Data: Hydrochlorothiazide induced gene mutations in mouse lymphoma cells and sister chromatid exchange in Chinese hamster cells. It induced mitotic recombination and nondisjunction in Aspergillus nidulans. Hydrochlorothiazide did not induce chromosomal aberrations in Chinese hamster cells in vitro or sex-linked recessive lethal mutations in Drosophila, and was not mutagenic to Salmonella typhimurium or E. coli.

Reproductive and Developmental Effects: The use of thiazides during pregnancy may produce hypoglycemia, hyponatremia, hyperbilirubinemia, decreased birth weight, bone marrow suppression with thrombocytopenia, and fetal death in newborn and fetus. Thiazide diuretics can also cause fetal or neonatal jaundice when used by pregnant women. Nine controlled trials involving almost 7000 individuals showed no evidence birth defects in infants born to mothers exposed to thiazide diuretics during pregnancy.

No adverse effects on fertility were seen in mice and rats fed diets including doses of hydrochlorothiazide up to 100 and 4 mg/kg, respectively. No defects in fetuses were observed in the offspring of pregnant rats administered 250 mg/kg on days 9, 10, 11, and 12 of gestation. Mice and rats gavaged with up to 3000 and 1000 mg/kg, respectively, produced no birth defects in their offspring, despite maternal toxicity.

SECTION 12 - ENVIRONMENTAL IMPACT INFORMATION

Ecological Information: Brachydanio rerio: LC50 (96 hr): >100 mg/L
Daphnia magna: EC50 (48 hr): >100 mg/L
Activated sludge: EC50 (3 hr): >100 mg/L

SECTION 13 - DISPOSAL INFORMATION

Waste must be disposed of in accordance with state, local and other environmental control regulations.

SECTION 14 - TRANSPORTATION INFORMATION

This product is not subject to the regulations for the safe transport of hazardous chemicals.
DOT: Not regulated
TDG: Not regulated
IATA: Not regulated
IMDG: Not regulated

SECTION 15 - REGULATORY INFORMATION

U.S. Regulatory Information: Not found

International Regulatory Information: EINECS # 200-403-3

SECTION 16 - OTHER DATA

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall INTAS be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if INTAS has been advised of the possibility of such damages.