Safety Data Sheet

Bisoprolol Fumarate and Hydrochlorothiazide Tablets, USP
Strength: 2.5 mg/6.25 mg, 5 mg/6.25 mg & 10 mg/6.25 mg
Pack Size: 2.5 mg/6.25 mg - HDPE Bottle: 30's, 100's 500's pack
5 mg/6.25 mg HDPE Bottle: 30's, 100's 500's pack
10 mg/6.25 mg - HDPE Bottle: 30's, 100's 500's pack

Revision No.: 00

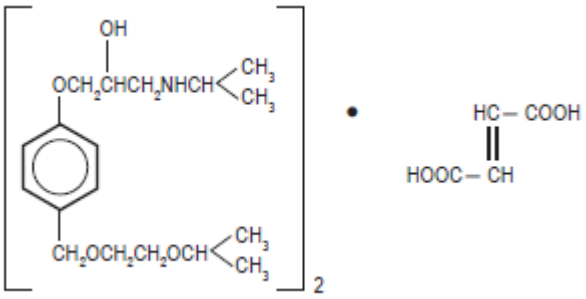
EMERGENCY OVERVIEW

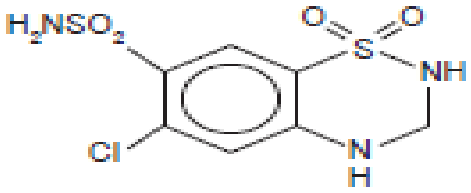
Each Bisoprolol Fumarate and Hydrochlorothiazide Tablets, USP intended for oral administration contains Bisoprolol Fumarate and Hydrochlorothiazide and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Section 1. Identification

Identification of the product

Product Name: Bisoprolol Fumarate and Hydrochlorothiazide Tablets, USP
Formula: (C18H31NO4)2·C4H4O4 & C7H8ClN3O4S2
Chemical Name:





Manufacturer / supplier identification

Company:	**Zydus Lifesciences Ltd., Matoda, India**
Address:	Zydus Lifescience Limited, Plot No- 1A/1 & 2, Pharmez Special Economic Zone, Sarkhej- Bavla N.H. No. 8A, Near Village Matoda, Tal. Sanand, Dist. Ahmedabad-382 213, India
Contact for information:	Tel: +91-79-26868100 Fax: +91-79-26868533
Emergency Telephone No.	Tel: +91-79-26868101
US Customer Service:	1 (877) 993 8779

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Recommended use / Therapeutic Category	Bisoprolol fumarate and hydrochlorothiazide tablets, USP are indicated for the treatment of hypertension. It combines two antihypertensive agents in a once-daily dosage: a synthetic beta1-selective (cardioselective) adrenoceptor blocking agent (bisoprolol fumarate) and a benzothiadiazine diuretic (hydrochlorothiazide).
Restriction on Use / Contraindications:	Bisoprolol fumarate and hydrochlorothiazide tablets are contraindicated in patients in cardiogenic shock, overt cardiac failure, second or third degree AV block, marked sinus bradycardia, anuria and hypersensitivity to either component of this product or to other sulfonamide-derived drugs.

Section 2. Hazard(s) Identification

Dose and Administration	Bisoprolol is an effective treatment of hypertension in once-daily doses of 2.5 mg to 40 mg, while hydrochlorothiazide is effective in doses of 12.5 mg to 50 mg. In clinical trials of bisoprolol/hydrochlorothiazide combination therapy using bisoprolol doses of 2.5 mg to 20 mg and hydrochlorothiazide doses of 6.25 mg to 25 mg, the antihypertensive effects increased with increasing doses of either component.
Adverse Effects	Bisoprolol fumarate/HCTZ 6.25 mg is well tolerated in most patients. Most adverse effects (AEs) have been mild and transient. In more than 65,000 patients treated worldwide with bisoprolol fumarate, occurrences of bronchospasm have been rare. Discontinuation rates for AEs were similar for bisoprolol fumarate/HCTZ 6.25 mg and placebo-treated patients.
Overdosage	There are limited data on overdose with bisoprolol fumarate and hydrochlorothiazide. However, several cases of overdose with bisoprolol fumarate have been reported (maximum: 2,000 mg).

	Bradycardia and/or hypotension were noted. Sympathomimetic agents were given in some cases and all patients recovered.
Pregnancy Comments	There are no adequate and well-controlled studies with bisoprolol fumarate and hydrochlorothiazide in pregnant women. Bisoprolol fumarate and hydrochlorothiazide should be used during pregnancy only if the potential benefit justifies the risk to the fetus.
Pregnancy Category	Category C

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component:		
Bisoprolol Fumarate	1.0 mg/day	104344-23-2
Hydrochlorothiazide	2.5 mg/day	58-93-5
Inactive ingredients:		
Colloidal Silicon Dioxide	Not Found	112926-00-8
Crospovidone	Not Found	9003-39-8
Microcrystalline Cellulose	Not Found	9004-34-6
Magnesium Stearate	Not Found	557-04-0
Butylated Hydroxyanisol	Not Found	25013-16-5
Acetone	Not Found	67-64-1
Dibasic Calcium Phosphate Anhydrous	Not Found	7757-93-9
Opadry White	Not Found	889676-18-0
Isopropyl Alcohol	Not Found	67-63-0
Methylene chloride	Not Found	75-09-2

Section 4. First -aid measures

In Case of Inhalation	Supply fresh air; consult doctor in case of complaints.
In Case of Skin Contact	Immediately wash with water and soap and rinse thoroughly.
In Case of Eye Contact	Rinse opened eye for several minutes under running water.
After swallowing	Rinse mouth. Do not induce vomiting. Call for a doctor immediately.

Section 5. Fire -fighting measures

Protective equipment	Wear self-contained respiratory protective device.

Special hazards arising from the substance or mixture	Formation of toxic gases is possible during heating or in case of fire.
Suitable extinguishing agents	CO_2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Section 6. Accidental release measure

Personal precautions & Protective equipment	Wear protective clothing.
Environmental precautions:	Inform respective authorities in case of seepage into water course or sewage system.
Methods and material for containment and cleaning up:	Dispose of contaminated material as waste according with mentioned procedure

Section 7. Handling and Storage

Precautions for safe handling	Store in cool, dry place in tightly closed receptacles.
Information about fire - and explosion protection	No special measures required
Requirements to be met by storerooms and receptacles:	Store in a cool location. Please refer to the manufacturer's certificate for specific storage and transport temperature conditions. Store only in the original receptacle. Keep container in a well-ventilated place. Keep away from sources of ignition and heat.
Information about storage in one common storage facility	Store away from foodstuffs

Section 8. Exposure control / Personal Protection

General protective and hygienic measures	Keep away from foodstuff, beverages and feed.
Eye Protection	Safety glasses

Protection of hands	The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Section 9. Physical and chemical properties

Physical States	**Description of Bisoprolol fumarate and Hydrochlorothiazide tablet 2.5 mg/6.25 mg** is Light yellow.to yellow colored with occasional greyish to black speckles, round shaped, film coated tablets debossed with "113" on one side and plain on other side **Description of Bisoprolol fumarate and Hydrochlorothiazide tablet 5 mg/6.25 mg** Light pink to pink colored round shaped, film, Description coated tablets debossed with "114" on one side and plain on other side. **Description of Bisoprolol fumarate and Hydrochlorothiazide tablet 10 mg/6.25 mg** White to off-white colored with occasional greyish to black speckles, round shaped, film coated tablets debossed with '115'' on one side and plain on other side**.**

Solubility / Miscibility in water	Ethanol, Methanol Easily soluble.	**Decomposition Temperature:**	No Data
Odour	Odourless	**Melting Point**	95 - 105 °C
Evaporation rate	No Data	**Vapour density**	No Data
Reactivity in water	No Data	**Vapour pressure**	No Data
% Volatile by volume	No Data	**Specific gravity**	No Data

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Section 10. Stability and Reactivity

Reactivity	Stable under normal conditions
Chemical stability	Stable under normal conditions
Thermal decomposition / conditions to be avoided:	Formation of toxic gases is possible during heating or in case of fire.
Possibility of hazardous reactions	No dangerous reactions known.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Formation of toxic gases is possible during heating or in case of fire.

Section 11. Toxicological information

LD/LC50 values relevant for classification:	Oral: LD50 - 678 mg/kg (mouse) 940 mg/kg (rat)

Section 12. Ecological information

Toxicity: Aquatic toxicity	EC50/48 h : 90 mg/l (daphnia) LC50/96 h : >100 mg/l (fish)
Persistence and degradability	Biodegradation: 4 %/28d

Section 13. Disposal Consideration

Dispose in accordance with local, state, and federal regulations

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG). In accordance with ADR / RID / IMDG / IATA / AND.

Section 15. Regulatory Information

Approved by USFDA & the ANDA Number is 215666.

Section 16. Other information

None

Date of issue: 22/12/23 **Supersedes edition:** New Edition

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.