

Safety Data Sheet

Bisoprolol Fumarate Tablets USP

Strength: 5mg & 10 mg

Pack Size: 5mg HDPE Bottle 30's and 100's

10 mg HDPE Bottle 30's and 100's

Revision No.: 00

EMERGENCY OVERVIEW

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

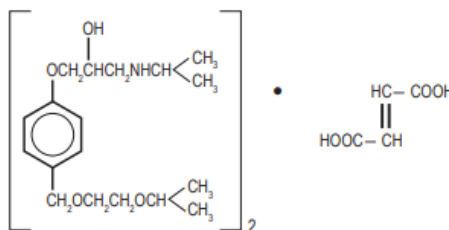
Section 1. Identification

Identification of the product

Product Name: Bisoprolol Fumarate Tablets USP

Formula: $(C_{18}H_{31}NO_4)_2 \cdot C_4H_4O_4$

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

**Recommended use /
Therapeutic Category**

Bisoprolol fumarate is a beta₁-selective (cardioselective) adrenoceptor blocking agent without significant membrane stabilizing activity or intrinsic sympathomimetic activity in its therapeutic dosage range. Cardioselectivity is not absolute, however and at higher doses (≥ 20 mg) bisoprolol fumarate also inhibits beta₂-adrenoceptors, chiefly located in the bronchial and vascular musculature; to retain selectivity it is therefore important to use the lowest effective dose

Safety Data Sheet

Bisoprolol Fumarate Tablets USP

Strength: 5mg & 10 mg

Pack Size: 5mg HDPE Bottle 30's and 100's

10 mg HDPE Bottle 30's and 100's

Revision No.: 00

Restriction on Use / Contraindications:

Bisoprolol fumarate is contraindicated in patients with cardiogenic shock, overt cardiac failure, second or third degree AV block and marked sinus bradycardia

Section 2. Hazard(s) Identification

Dose and Administration

The dose of Bisoprolol fumarate tablets, USP must be individualized to the needs of the patient. The usual starting dose is 5 mg once daily. In some patients, 2.5 mg may be an appropriate starting dose. If the antihypertensive effect of 5 mg is inadequate, the dose may be increased to 10 mg and then, if necessary, to 20 mg once daily.

Adverse Effects

Central Nervous System: Dizziness, unsteadiness, vertigo, syncope, headache, paresthesia, hypoesthesia, hyperesthesia, somnolence, sleep disturbances, anxiety/restlessness, and decreased concentration/ memory.

Autonomic Nervous System: Dry mouth.

Cardiovascular Bradycardia: Palpitations and other rhythm disturbances, cold extremities, claudication, hypotension, orthostatic hypotension, chest pain, congestive heart failure, dyspnea on exertion.

Psychiatric: Vivid dreams, insomnia, depression.

Gastrointestinal: Gastric/epigastric/abdominal pain, gastritis, dyspepsia, nausea, vomiting, diarrhoea, constipation, peptic ulcer.

Musculoskeletal: Muscle/joint pain, arthralgia, back/neck pain, muscle cramps, twitching/tremor.

Skin: Rash, acne, eczema, psoriasis, skin irritation, pruritus, flushing, sweating, alopecia, dermatitis, angioedema, exfoliative dermatitis, cutaneous vasculitis.

Safety Data Sheet

Bisoprolol Fumarate Tablets USP

Strength: 5mg & 10 mg

Pack Size: 5mg HDPE Bottle 30's and 100's

10 mg HDPE Bottle 30's and 100's

Revision No.: 00

Special Senses: Visual disturbances, ocular pain/pressure, abnormal lacrimation, tinnitus, decreased hearing, earache, taste abnormalities.

Respiratory: Asthma/bronchospasm, bronchitis, coughing, dyspnea, pharyngitis, rhinitis, sinusitis, URI.

Central Nervous System: Reversible mental depression progressing to catatonia, hallucinations, an acute reversible syndrome characterized by disorientation to time and place, emotional lability, slightly clouded sensorium.

Overdosage

If overdose occurs, bisoprolol fumarate therapy should be stopped and supportive and symptomatic treatment should be provided. Limited data suggest that bisoprolol fumarate is not dialyzable. Based on the expected pharmacologic actions and recommendations for other beta-blockers, the following general measures should be considered when clinically warranted:

Bradycardia: Administer IV atropine. If the response is inadequate, isoproterenol or another agent with positive chronotropic properties may be given cautiously. Under some circumstances, transvenous pacemaker insertion may be necessary.

Hypotension: IV fluids and vasopressors should be administered. Intravenous glucagon may be useful.

Heart Block (second or third degree): Patients should be carefully monitored and treated with isoproterenol infusion or transvenous cardiac pacemaker insertion, as appropriate.

Congestive Heart Failure: Initiate conventional therapy (i.e., digitalis, diuretics, inotropic agents, vasodilating agents).

Safety Data Sheet

Bisoprolol Fumarate Tablets USP

Strength: 5mg & 10 mg

Pack Size: 5mg HDPE Bottle 30's and 100's

10 mg HDPE Bottle 30's and 100's

Revision No.: 00

Bronchospasm: Administer bronchodilator therapy such as isoproterenol and/or aminophylline.

Hypoglycemia: Administer IV glucose.

Pregnancy Comments

There are no adequate and well-controlled studies in pregnant women. Bisoprolol fumarate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Pregnancy Category

Category C

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component:		
Bisoprolol Fumarate	250mcg/day	66722-44-9
Inactive ingredients:		
Microcrystalline Cellulose 102	Not Found	9004-34-6
Butylated Hydroxyanisol	Not Found	25013-16-5
Dibasic Calcium Phosphate anhydrous	Not Found	7757-93-9
Magnesium stearate	Not Found	557-04-0
Colloidal Silicon Dioxide	Not Found	7631-86-9
Crospovidone	Not Found	9003-39-8
Opadry White 03F580108	Not Found	889676-18-0
Methylene Chloride	Not Found	75-09-2
Isopropyl Alcohol	Not Found	67-63-0

Section 4. First -aid measures

In Case of Inhalation

Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

In Case of Skin Contact

Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

In Case of Eye Contact

Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.

Safety Data Sheet

Bisoprolol Fumarate Tablets USP

Strength: 5mg & 10 mg

Pack Size: 5mg HDPE Bottle 30's and 100's

10 mg HDPE Bottle 30's and 100's

Revision No.: 00

In Case of Ingestion	Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.
-----------------------------	---

Section 5. Fire -fighting measures

Suitable Extinguishing Media	Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray. Use water spray to cool fire-exposed containers.
-------------------------------------	--

Fire Fighting Instructions	As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.
-----------------------------------	---

Unsuitable Extinguishing media	A solid water stream may be inefficient.
---------------------------------------	--

Flammable Properties & Hazards:	No data available.
--	--------------------

Section 6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	Avoid raising and breathing dust, and provide adequate ventilation. As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).
--	--

Environmental precautions:	Take steps to avoid release into the environment, if safe to do so.
-----------------------------------	---

Methods and material for containment and cleaning up:	Contain spill and collect, as appropriate. Transfer to a chemical waste container for disposal in accordance with local regulations.
--	--

Section 7. Handling and Storage

Precautions To Be Taken in Handling:	Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid prolonged or repeated exposure
---	--

Precautions To Be Taken in Storing	Keep container tightly closed. Store in accordance with information listed on the product insert
---	--

Section 8. Exposure controls / personal protection

Respiratory Protection:	NIOSH approved respirator, as conditions warrant.
--------------------------------	---

Eye/face protection:	Safety glasses
-----------------------------	----------------

Safety Data Sheet

Bisoprolol Fumarate Tablets USP

Strength: 5mg & 10 mg

Pack Size: 5mg HDPE Bottle 30's and 100's

10 mg HDPE Bottle 30's and 100's

Revision No.: 00

Over Protective Clothing:	Lab coat
Protective Gloves:	Compatible chemical-resistant gloves
Work/Hygienic/Maintenance Practices:	Do not take internally. Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Wash thoroughly after handling
Engineering controls	Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

Section 9. Physical and chemical properties

Physical States	A crystalline solid		
Solubility	No Data	Decomposition Temperature:	No Data
Boiling point	No Data	Melting Point	No Data
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

Section 10. Stability and Reactivity

Stable	Stable if stored in accordance with information listed on the product insert.
Reactivity	No data available
Polymerization	Will not occur
Hazardous reactions	No dangerous reaction known under conditions of normal use.
Decomposition products	Carbon dioxide, carbon monoxide, nitrogen oxides
Incompatible materials	Strong Oxidizing agent

Section 11. Toxicological information

Information on Toxicological Effects	The toxicological effects of this product have not been thoroughly studied.
---	---

Section 12. Ecological information

Toxicity	Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.
-----------------	--

Safety Data Sheet

Bisoprolol Fumarate Tablets USP

Strength: 5mg & 10 mg

Pack Size: 5mg HDPE Bottle 30's and 100's

10 mg HDPE Bottle 30's and 100's

Revision No.: 00

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 215680

Section 16. Other information

None

Date of issue: 17/11/22

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.