Safety Data Sheet
Buspirone Hydrochloride Tablets, USP

Strength: 5 mg,10 mg, 15mg, 30mg **Revision No.:** 02
Pack Size: 100/500/1000 Tablets per bottle & Unit dose blisters of 10X10 Tablet for 5 mg and 10mg.
60/100/180/500/1000 Tablets per bottle & Unit dose blisters of 10X10 Tablet for 15 mg.
60/500/1000 Tablets per bottle & Unit dose blisters of 10X10 Tablet for 30 mg .

EMERGENCY OVERVIEW

Each Buspirone Hydrochloride Tablets intended for oral administration contains Buspirone hydrochloride and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

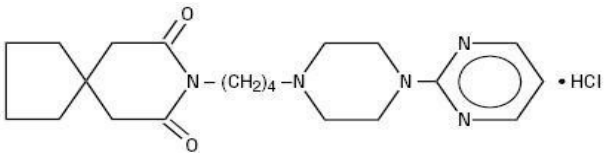
Section 1. Identification

Identification of the product

Product name: **Buspirone Hydrochloride Tablets, USP**

Formula: $C_{21}H_{31}N_5O_2$•HCl

Chemical Name: 8-[4-[4-(2-pyrimidinyl)-1-piperazinyl]butyl]-8-azaspiro[4.5] decane-7,9-dione monohydrochloride



Manufacturer / supplier identification

Company: **Cadila Healthcare Ltd. Ahmedabad, India**

Address: Sarkhej – Bavla. N.H. 8A, Moraiya. Tal. Sanand. Dist. Ahmedabad – 382210. State: Gujarat. India

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Recommended use / Therapeutic Category Antianxiety agent.

Restriction on Use / Contraindications: Buspirone hydrochloride tablets are contraindicated in patients hypersensitive to buspirone hydrochloride.

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Section 2. Hazard(s) Information

Dose and Administration	The recommended initial dose is 15 mg daily (7.5 mg b.i.d.). To achieve an optimal therapeutic response, at intervals of 2 to 3 days the dosage may be increased 5 mg per day, as needed. The maximum daily dosage should not exceed 60 mg per day.
Adverse Effects	The more commonly observed untoward events associated with the use of buspirone hydrochloride tablets not seen at an equivalent incidence among placebo-treated patients include dizziness, nausea, headache, nervousness, lightheadedness, and excitement.
Over Dose Effect	In clinical pharmacology trials, doses as high as 375 mg/day were administered to healthy male volunteers. As this dose was approached, the following symptoms were observed: nausea, vomiting, dizziness, drowsiness, miosis, and gastric distress. A few cases of overdosage have been reported, with complete recovery as the usual outcome. No deaths have been reported following overdosage with buspirone hydrochloride tablets alone. Rare cases of intentional overdosage with a fatal outcome were invariably associated with ingestion of multiple drugs and/or alcohol, and a causal relationship to buspirone could not be determined. Toxicology studies of buspirone yielded the following LD 50 values: mice, 655 mg/kg; rats, 196 mg/kg; dogs, 586 mg/kg; and monkeys, 356 mg/kg. These dosages are 160 to 550 times the recommended human daily dose.
Contraindications	Buspirone hydrochloride tablets are contraindicated in patients hypersensitive to buspirone hydrochloride.
Medical condition	**Major Depressive Disorder** Bupropion hydrochloride extended-release tablets, USP (XL) are indicated for the treatment of major depressive disorder (MDD), as defined by the Diagnostic and Statistical Manual (DSM). The efficacy of the immediate-release formulation of bupropion was established in two 4 week controlled inpatient trials and one 6 week controlled outpatient trial of adult patients with MDD. The efficacy of the sustained-release formulation of bupropion in the maintenance treatment of MDD was established in a long-term (up to 44 weeks), placebo-controlled trial in patients who had responded to bupropion in an 8 week study of acute treatment [see *Clinical Studies (14.1)*]. **Seasonal Affective Disorder** Bupropion hydrochloride extended-release tablets, USP (XL) are indicated for the prevention of seasonal major depressive episodes in patients with a diagnosis of seasonal affective disorder (SAD). The efficacy of bupropion hydrochloride extended-release tablets in the prevention of seasonal major depressive episodes was established in 3 placebo-controlled trials in adult outpatients with a history of MDD with an autumn-winter seasonal pattern

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Pregnancy Comments No fertility impairment or fetal damage was observed in reproduction studies performed in rats and rabbits at buspirone doses of approximately 30 times the maximum recommended human dose. In humans, however, adequate and well-controlled studies during pregnancy have not been performed. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Pregnancy Category **B**

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component :		
Buspirone hydrochloride	Not Found	33386-08-2
Inactive Ingredients :		
Colloidal silicon dioxide	Not Found	7631-86-9
Magnesium stearate	Not Found	577-04-0
Microcrystalline cellulose	Not Found	9004-34-6
Lactose monohydrate	Not Found	5989-81-1
Sodium starch glycolate	Not Found	9063-38-1

Section 4. First - aid measures

General

Inhalation

Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

Contact with skin

Immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.

Ingestion

If swallowed, wash out mouth with water, provided person is concious. Seek medical advice

Remove and wash/dispose of contaminated clothing promptly.

Overdose Treatment	General symptomatic and supportive measures should be used along with immediate gastric lavage. Respiration, pulse, and blood pressure should be monitored as in all cases of drug overdosage. No specific antidote is known to buspirone, and dialyzability of buspirone has not been determined.

Section 5. Fire - fighting measures

Flash point	Not Found	**Upper Flammable Limit:**	Not Found
Auto-Ignition Temperature:	Not Found	**Lower Flammable Limit:**	Not Found
Extinguishing Media	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.	**Fire and Explosion Hazard**	This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build-up of static electricity.

Fire Fighting Procedure	As with all fires, evacuate personnel to a safe area. Fire fighter should use self- contained breathing equipment and protective clothing.

Section 6. Accidental Release Measures

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

Section 7. Handling and Storage

Storage	Store at 20° to 25° C (68° to 77° F). Dispense in a tight, light-resistant container.
Incompatibilities:	No Data available.

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Section 8. Exposure controls / personal protection

Respiratory Protection	Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.
Skin Protection	Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.
Eye protection	Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.
Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.
Engineering Control	Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Accidental Release Measures of this MSDS.

Section 9. Physical and chemical properties

Appearance

Buspirone Hydrochloride Tablets USP, 5 mg are white to off-white, capsule shaped, flat- faced, beveled-edge tablets debossed with bisect on one side; one side of bisect is debossed with ‘ZE’ and another is debossed with ‘36’ and other side is plain

Buspirone Hydrochloride Tablets USP, 10 mg are white to off-white, capsuleshaped, flat-faced, beveled-edge tablets debossed with bisect on one side; one side of bisect is debossed with ‘ZE’ and another is debossed with ‘37’ and other side is plain

Buspirone Hydrochloride Tablets USP, 15 mg are white to off-white, capsuleshaped, flat-faced, beveled-edge tablets, bisected on one side and trisected on other side. The trisected side of tablet is debossed with ‘5’ on each trisect segment. The bisected side is debossed with ‘ZE’, on one bisect and ‘38’ on other bisect segment

Buspirone Hydrochloride Tablets USP, 30 mg are white to off-white, capsuleshaped, flat-faced, beveled-edge tablets, bisected on one side and trisected on other side. The trisected side of tablet is debossed with ‘10’ on each trisect segment. The bisected side is debossed with ‘ZE’, on one bisect and ‘39’ on other bisect segment.

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Solubility in water	No Data Available	**Odour**	Odourless
Boiling point	No Data Available	**Melting Point**	No Data Available
Evaporation rate	No Data Available	**Vapour density**	No Data Available
Reactivity in water	No Data Available	**Evaporation rate**	No Data Available
% Volatile by volume	No Data Available	**Specific gravity**	No Data Available
		Vapour pressure	No Data Available

Other information Buspirone hydrochloride, USP is a white crystalline powder. It is very soluble in water; freely soluble in methanol and in methylene chloride; sparingly soluble in ethanol and in acetonitrile; very slightly soluble in ethyl acetate and practically insoluble in hexanes. Its molecular weight is 422. Chemically, buspirone hydrochloride is 8-[4-[4-(2-pyrimidinyl)-1-piperazinyl] butyl]-8- azaspiro [4.5]decane-7,9-dione monohydrochloride. The molecular formula $C_{21}H_{31}N_5O_2$•HCl

Section 10. Stability and Reactivity

Condition to avoid	Avoid exposure to extreme heat, light and moisture.	**Stable**	Stable under normal ambient and anticipated storage and handling conditions.
Decomposition Products	No Data Available	**Hazardous Reaction**	No data available.
Incompatibilities:	No Data Available		

Section 11. Toxicological information

General Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.

Target organ Eye contact, Skin contact and inhalation is not great risk as this product is tablet.

Other Toxicology studies of buspirone yielded the following LD 50 values: mice, 655 mg/kg;rats, 196 mg/kg; dogs, 586 mg/kg; and monkeys, 356 mg/kg. These dosages are 160 to 550 times the recommended human daily dose.

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Section 12. Ecological information

Do not allow product to enter drinking water supplies, waste water or soil

Section 13. Disposal Consideration

Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).

Section 15. Regulatory Information

Generic Medicine. Approved by USFDA & the ANDA Number is 078888

Section 16. Other information

None

Date of issue: 28/05/2015 **Supersedes edition of:** 01

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