Material Safety data sheet

Tamsulosin Hydrochloride Capsules

Strength: 0.4mg.

NDC 68382-132-06 in bottle of 30 capsules
NDC 68382-132-14 in bottle of 60 capsules
NDC 68382-132-16 in bottle of 90 capsules
NDC 68382-132-01 in bottle of 100 capsules
NDC 68382-132-05 in bottle of 500 capsules
NDC 68382-132-10 in bottle of 1000 capsules

Revision No.: 01

EMERGENCY OVERVIEW

Tamsulosin Hydrochloride Capsules contain Tamsulosin 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 of the substance

Identification of the product

Product name:	**Tamsulosin Hydrochloride Capsules**
Formula:	$C_{20}H_{28}N_2O_5S \bullet HCl$
Chemical Name:	(-)-(*R*)-5-[2-[[2-(*o*-Ethoxyphenoxy) ethyl]amino]propyl]-2-methoxybenzenesulfonamide, monohydrochloride.
Therapeutic Category	An antagonist of alpha$_{1A}$ adrenoceptors

Manufacturer / supplier identification

Company:	**Cadila Healthcare Ltd. Ahmedabad, India**
Contact for information:	Tel.: +91 79 6868100 Fax: +91 79 3750319
Emergency telephone No.	Tel.: +91 79 6868100

Section 2. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Tamsulosin Hydrochloride	Not Found	106463-17-6
Gelatin	Not Found	9000-70-8
Methacrylic Acid co polymer	Not Found	79-41-4
Microcrystalline Cellulose	Not Found	9004-34-6
Polysorbate 80	Not Found	9005-65-6
Talc	Not Found	14807-96-6
Titanium Dioxide	Not Found	13463-67-7
Triacetin	Not Found	102-76-1
Yellow Iron Oxide	Not Found	51274-00-1

Component	Exposure Limit	CAS No.
Black Iron Oxide	Not Found	1317-61-9
D & C Yellow #10	Not Found	8004-92-0
FD & C Blue # 1	Not Found	--
FD & C Red # 40	Not Found	--
FD & C Yellow # 6	Not Found	--

Section 3. Health Hazards Information

Dose and Administration

Tamsulosin hydrochloride capsules, 0.4 mg once daily is recommended as the dose for the treatment of the signs and symptoms of BPH. It should be administered approximately one-half hour following the same meal each day.

For those patients who fail to respond to the 0.4 mg dose after two to four weeks of dosing, the dose of tamsulosin hydrochloride capsules can be increased to 0.8 mg once daily. If tamsulosin hydrochloride capsules administration is discontinued or interrupted for several days at either the 0.4 mg or 0.8 mg dose, therapy should be started again with the 0.4 mg once daily dose.

Adverse Effects

The incidence of treatment-emergent adverse events has been ascertained from six short-term U.S. and European placebo-controlled clinical trials in which daily doses of 0.1 to 0.8 mg tamsulosin hydrochloride capsules were used. These studies evaluated safety in 1783 patients treated with tamsulosin hydrochloride capsules and 798 patients administered placebo. Table 3 summarizes the treatment-emergent adverse events that occurred in ≥2% of patients receiving either tamsulosin hydrochloride capsules 0.4 mg, or 0.8 mg and at an incidence numerically higher than that in the placebo group during two 13-week U.S. trials (US92-03A and US93-01) conducted in 1487 men.

Over Dose Effect	overdosage of tamsulosin hydrochloride capsules lead to hypotension, support of the cardiovascular system is of first importance. Restoration of blood pressure and normalization of heart rate may be accomplished by keeping the patient in the supine position. If this measure is inadequate, then administration of intravenous fluids should be considered. If necessary, vasopressors should then be used and renal function should be monitored and supported as needed. Laboratory data indicate that tamsulosin hydrochloride is 94% to 99% protein bound; therefore, dialysis is unlikely to be of benefit. One patient reported an overdose of thirty 0.4 mg tamsulosin hydrochloride capsules. Following the ingestion of the capsules, the patient reported a severe headache.
Contraindications	Tamsulosin hydrochloride capsules are contraindicated in patients known to be hypersensitive to tamsulosin hydrochloride or any component of tamsulosin hydrochloride capsules
Pregnancy Comments	***Teratogenic Effects,*** Administration of tamsulosin hydrochloride to pregnant female rats at dose levels up to 300 mg/kg/day (approximately 50 times the human therapeutic AUC exposure) revealed no evidence of harm to the fetus. Administration of tamsulosin hydrochloride to pregnant rabbits at dose levels up to 50 mg/kg/day produced no evidence of fetal harm. Tamsulosin hydrochloride capsules are not indicated for use in women.
Pregnancy Category	**B**

Section 4. First aid measures

General	Remove from exposure. Remove contiminated Clothing. Person devloping serious hypersensitivity reaction must receive medical attention.
Overdose Treatment	Should overdosage of tamsulosin hydrochloride capsules lead to hypotension, support of the cardiovascular system is of first importance. Restoration of blood pressure and normalization of heart rate may be accomplished by keeping the patient in the supine position. If this measure is inadequate, then administration of intravenous fluids should be considered. If necessary, vasopressors should then be used and renal function should be monitored and supported as needed. Laboratory data indicate that tamsulosin hydrochloride is 94% to 99% protein bound; therefore, dialysis is unlikely to be of benefit.

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. Storage / Spill / Disposal Measures

Storage	Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
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.
Disposal	Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 7. Exposure controls and 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.

Section 8. Physical and chemical properties

Appearance	Tamsulosin Hydrochloride Capsules, 0.4 mg are white to off-white free flowing pellets filled in size '2' empty hard gelatin capsules with green colored cap printed with "ZA-18" in black ink and peach colored body printed with "0.4 mg" in black ink		
Odour	Odourless	**Melting Point**	No Data Available
Solubility in water	No Data Available	**Vapour density**	No Data Available
Boiling point	No Data Available	**Evaporation rate**	No Data Available
Evaporation rate	No Data Available	**Specific gravity**	No Data Available
Reactivity in water	No Data Available	**Vapour pressure**	No Data Available
% Volatile by volume	No Data Available		
Other information	Tamsulosin hydrochloride, USP is a white crystalline powder that melts with decomposition at approximately 230°C. It is sparingly soluble in water and methanol, slightly soluble in glacial acetic acid and ethanol, and practically insoluble in ether.		

Section 9. Physical Hazards

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 10. Toxicological information

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	Refer contraindication and adverse effect.
other	Not Available

Section 11. Ecological information

No data available on Ecotoxicity

Section 12. Other information

None

Date of issue: 18/01/10 **Supersedes edition of:** New Addition

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.