

**Safety Data Sheet**  
**Tamsulosin Hydrochloride Capsules**

**Strength:** 0.4mg.   **Pack Size:** 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

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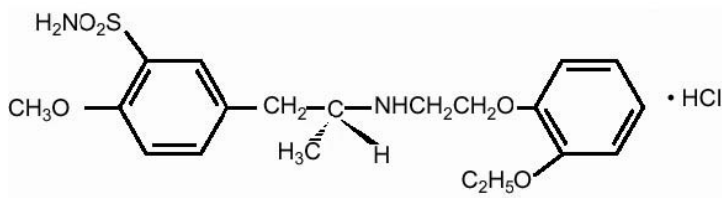
**EMERGENCY OVERVIEW**

Each Tamsulosin Hydrochloride Capsules intended for oral administration contains 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**

**Identification of the product**

**Product name:** Tamsulosin Hydrochloride Capsules  
**Formula:** C<sub>20</sub>H<sub>28</sub>N<sub>2</sub>O<sub>5</sub>S • HCl  
**Chemical Name:** (-)-(R)-5-[2-[[2-(o-Ethoxyphenoxy) ethyl]amino]propyl]-2-methoxybenzenesulfonamide, 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  
**Contact for information:** Tel.: +91 79 6868100 Fax: +91 79 3750319  
**Emergency Telephone No.** Tel.: +91 79 6868100  
**Recommended use / Therapeutic Category** An antagonist of alpha1A adrenoceptors.  
**Restriction on Use / Contraindications** Tamsulosin hydrochloride capsules are contraindicated in patients known to be hypersensitive to tamsulosin hydrochloride or any component of tamsulosin hydrochloride capsules.

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**Section 2. Hazard(s) 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  $\geq 2\%$  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)

**Over Dose Effect**

Overdose 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.

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**Medical condition**

- Advise patients about the possibility of symptoms related to postural hypotension and to avoid situations where injury could result should syncope occur.
- Should not be used in combination with strong inhibitors of CYP3A4. Use with caution in combination with moderate inhibitors of CYP3A4, with strong or moderate inhibitors of CYP2D6, in patients known to be CYP2D6 poor metabolizers, or in combination with other cytochrome P450 inhibitors.
- Should not be used in combination with other alpha adrenergic blocking agents.
- Exercise caution with concomitant administration of warfarin.
- Advise patients about the possibility and seriousness of priapism.
- Intraoperative Floppy Iris Syndrome has been observed during cataract and glaucoma surgery in some patients. Advise patients considering cataract or glaucoma surgery to tell their ophthalmologist that they have taken tamsulosin hydrochloride capsules.
- Advise patients to be screened for the presence of prostate cancer prior to treatment and at regular intervals afterwards.

**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 3.      Composition / information on ingredients**

<b>Component</b>	<b>Exposure Limit</b>	<b>CAS No.</b>
<b>Principle Component :</b>		
Tamsulosin Hydrochloride	Not Found	106463-17-6
<b>Inactive Ingredients :</b>		
Gelatin	Not Found	9000-70-8
Methacrylic Acid co polymer	Not Found	79-41-4

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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
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 Red # 6	Not Found	--

**Section 4. First - aid measures**

**General**                      Remove from exposure. Remove contaminated Clothing. Person developing 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

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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) [See USP Controlled Room Temperature].

**Incompatibilities:**                        No data available.

**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**                        Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation. HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.

**Section 9.      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

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printed with “ZA-18” in black ink and peach colored body printed with “0.4 mg” in black ink.

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

**Other information**    The molecular formula of tamsulosin hydrochloride is C<sub>20</sub>H<sub>28</sub>N<sub>2</sub>O<sub>5</sub>S • HCl. The Molecular weight of tamsulosin hydrochloride is 444.98. 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 10. Stability and Reactivity**

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

**Section 11. Toxicological information**

<b>General</b>	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.
<b>Target organ</b>	Refer contraindication and adverse effect
<b>Other</b>	Not available

**Section 12. Ecological information**

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

**Section 13. Disposal Consideration**

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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 078225

**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.