SAFETY DATA SHEET

Flomax® capsules (finished product)

SECTION 1. IDENTIFICATION

Product name : Flomax® capsules (finished product)

Synonyms : Active ingredient: Tamsulosin hydrochloride
Flomax® 0.4 mg tablets, Flomax® 0.025 mg capsules, Flomax® 0.1 mg capsules, Flomax® 0.2 mg capsules, Flomax® 0.4 mg capsules, Flomax® 0.025 mg capsules, Flomax® 0.1 mg capsules, Flomax® 0.2 mg capsules, Flomax® 0.4 mg capsules, ALNA® capsules, ALNA® Ocas® tablets, PRADIF® film coated tablets, PRADIF® capsules, PRADIF Ocas® film coated tablets, PRADIF® T film coated tablets, JOSIR® capsules, MECIR® film coated tablets, SECOTEX Ocas® film coated tablets, SECOTEX® capsules, TAMSULOSINA® capsules, TOCAS® film coated tablets, UROLOSIN® capsules

Manufacturer or supplier's details

Company name of supplier : Boehringer Ing. Pharma GmbH & Co.KG
Address : Binger Str. 173
Ingelheim am Rhein 07 55216
Telephone : +498007790900
Prepared by : EHS-Services@Boehringer-Ingelheim.com
Emergency telephone number : Int. Emergency Telephone number: +1 703-527-3887
Chemtrec 24-hours

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Safety Data Sheet only for the professional user.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards
The pharmacological effect of the medicament has to be considered (see package leaflet). This drug is not subject to the labelling requirements under the Globally Harmonized System (GHS)

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture
Chemical nature : organic

Substance name : Active ingredient: Tamsulosin hydrochloride

### Hazardous components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tamsulosin hydrochloride</td>
<td>Benzenesulfonamide, 5-[(2R)-2-[[2-(2-ethoxyphenoxy)ethyl]amino]propyl]-2-methoxy-, hydrochloride (1:1)</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

### SECTION 4. FIRST AID MEASURES

**General advice**
In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). First Aid responders should pay attention to self-protection and use the recommended protective clothing. Remove from exposure, lie down. Victim to lie down in the recovery position, cover and keep him warm.

**If inhaled**
Move to fresh air.

**In case of skin contact**
Wash off immediately with plenty of water.

**In case of eye contact**
Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing.

**If swallowed**
Rinse mouth. Drink plenty of water.

**Most important symptoms and effects, both acute and delayed**
No information available.

**Notes to physician**
Observe the summary of product characteristics of proprietary medicinal products. Symptomatic treatment (decontamination, vital functions).

### SECTION 5. FIREFIGHTING MEASURES

**Suitable extinguishing media**
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Water, Dry chemical, Foam, Carbon dioxide (CO2).
SAFETY DATA SHEET
Flomax® capsules (finished product)

Specific hazards during fire-fighting:
In case of fire and/or explosion do not breathe fumes. Can be released in case of fire:
- Carbon oxides
- Nitrogen oxides (NOx)
- Sulphur oxides
- Hydrogen chloride gas

Further information:
Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

Special protective equipment for firefighters:
In the event of fire, wear self-contained breathing apparatus. complete suit protecting against chemicals

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
Wear personal protective equipment. Ensure adequate ventilation.

Environmental precautions:
Do not flush into surface water or sanitary sewer system.

Methods and materials for containment and cleaning up:
Pick up and transfer to properly labelled containers.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion:
No special protective measures against fire required.

Advice on safe handling:
Provide sufficient air exchange and/or exhaust in work rooms.

Conditions for safe storage:
No special storage conditions required.

Materials to avoid:
Keep away from food, drink and animal feedingstuffs. Advice on Segregation

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>Basis</th>
<th>Category</th>
<th>Values</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>(R)-5-(2((2-(2-Ethoxyphenoxy)ethyl)amino)propyl)2-methoxybenzenesulfamide Monohydrochloride 106463-17-6</td>
<td>BIEL</td>
<td>3B</td>
<td>4 µg/m3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BIPC</td>
<td>1a</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Abbreviations:
BIEL = Boehringer Ingelheim Exposure Limit (internal value)
BI-STEL = Boehringer Ingelheim Short-Term Exposure Limit (Excursion limit)
BIPC = Boehringer Ingelheim Pregnancy Category
BIPC 1a: No risk of harm to the unborn is to be expected, when the exposure does not exceed the BIEL value. Available data in animals and/or humans indicate that the compound does not pose a special risk to the unborn.

Engineering measures
Local exhaust

Personal protective equipment
Respiratory protection: No personal respiratory protective equipment normally required. Respirator must be worn if exposed to dust. Respirator with a dust filter particle filter P2 (EN 143)
Use NIOSH approved respiratory protection.

Hand protection
Material: Nitrile rubber
Break through time: 480 min
Glove thickness: 0.43 mm
Directive: Protective gloves against chemicals and micro-organisms
Protective index: Class 6

Eye protection
Safety glasses with side-shields

Skin and body protection
Laboratory: laboratory coat; factory: disposable Overall.

Protective measures
Handle in accordance with good industrial hygiene and safety practice.
Do not breathe dust.
Avoid contact with skin, eyes and clothing.
Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.

Hygiene measures
General industrial hygiene practice.
Wash hands and face before breaks and immediately after handling the product.
Keep working clothes separately.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: solid
Colour: No data available
Odour: No data available
Odour Threshold: No data available
pH: No data available
Melting point/range: Not applicable
Boiling point/boiling range: Not applicable
Flash point: Not applicable
Evaporation rate: Not applicable
Flammability (solid, gas): No data available
Self-ignition: No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapour pressure: Not applicable
Relative vapour density: Not applicable
Relative density: No data available
Bulk density: No data available
Solubility(ies)
  Water solubility: No data available
Partition coefficient: n-octanol/water: No data available
Auto-ignition temperature: No data available
Decomposition temperature: No data available
Viscosity
  Viscosity, dynamic: Not applicable
Explosive properties: Not tested
Oxidizing properties: No data available

SECTION 10. STABILITY AND REACTIVITY
Reactivity: No dangerous reaction known under conditions of normal use.
Chemical stability : No decomposition if stored and applied as directed.

Possibility of hazardous reactions : No dangerous reaction known under conditions of normal use.

Conditions to avoid : Extremes of temperature and direct sunlight.

Incompatible materials : No data available

Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:
Tamsulosin hydrochloride:
Acute oral toxicity : LD50 (Rat, male): = 650 mg/kg
LD50 (Rat, female): = 787 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation
Not classified based on available information.

Components:
Tamsulosin hydrochloride:
Remarks: No data available

Serious eye damage/eye irritation
Not classified based on available information.

Components:
Tamsulosin hydrochloride:
Species: Rabbit
Result: No skin irritation
Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Tamsulosin hydrochloride:
Species: Guinea pig
Result: No alert for skin sensitization

Germ cell mutagenicity
Not classified based on available information.

Components:

Tamsulosin hydrochloride:
Genotoxicity in vitro:
Test Type: Ames-test
Test system: Salmonella typhimurium
Result: negative
Remarks: The substance was not mutagenic in bacteria.

Test Type: Chromosomal aberration test
Test system: CHO (Chinese hamster ovary)
Result: positive

Test Type: Mouse lymphoma assay
Test system: mouse lymphoma cells
Result: negative

Test Type: Cytogenetic assay
Test system: Human lymphocytes
Result: positive

Genotoxicity in vivo:
Test Type: Micronucleus test
Species: Mouse
Result: negative
Remarks: No mutagenic effects reported.

Test Type: Sister chromatid exchange assay
Species: Chinese hamster
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Tamsulosin hydrochloride:
Remarks: No data available

IARC
No component of this product present at levels greater than or
equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP**

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**Reproductive toxicity**

Not classified based on available information.

**Components:**

**Tamsulosin hydrochloride:**

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Not classified based on available information.

**Aspiration toxicity**

Not classified based on available information.

**Components:**

**Tamsulosin hydrochloride:**

No data available

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**SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**Tamsulosin hydrochloride:**

Toxicity to fish : LC50: = 750 mg/l

Exposure time: 96 h

GLP: yes

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia (water flea)): = 180 mg/l

GLP: yes

Toxicity to algae : Remarks: No data available

Toxicity to fish (Chronic toxicity) : Remarks: No data available
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available

Toxicity to microorganisms : Remarks: No data available

Persistence and degradability
No data available

Bioaccumulative potential

Components:
Tamsulosin hydrochloride:
Partition coefficient: n-octanol/water : log Pow: 0.5 (37 °C)

Mobility in soil
No data available

Other adverse effects

Product:
Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents. Uncontaminated packaging can be recycled.

SECTION 14. TRANSPORT INFORMATION

International Regulations

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations
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49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know Act

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component TPQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARA 311/312 Hazards</td>
<td>No SARA Hazards</td>
<td></td>
</tr>
<tr>
<td>SARA 313</td>
<td>This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.</td>
<td></td>
</tr>
</tbody>
</table>

Clean Air Act
This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act
This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations
Massachusetts Right To Know
No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know
Non-hazardous galenic excipients, solid Not Assigned

The components of this product are reported in the following inventories:
REACH : Not in compliance with the inventory
DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.
  Tamsulosin hydrochloride
  Non-hazardous galenic excipients, solid
AICS : Not in compliance with the inventory
SAFETY DATA SHEET

Flomax® capsules (finished product)

Version 1.1
Revision Date: 10/13/2017
SDS Number: 00000023782
Date of last issue: 09/26/2017
Date of first issue: 09/26/2017

NZIoC: Not in compliance with the inventory
ENCS: Not in compliance with the inventory
ISHL: Not in compliance with the inventory
KECI: Not in compliance with the inventory
PICCS: Not in compliance with the inventory
IECSC: Not in compliance with the inventory
TCSI: Not in compliance with the inventory
TSCA: Not On TSCA Inventory

TSCA list
No substances are subject to a Significant New Use Rule.
No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

Further information

NFPA:

Flammability

Health

1

0

Special hazard.

HMIS® IV:

HEALTH / 0

FLAMMABILITY 1

PHYSICAL HAZARD 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations
AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification
SAFETY DATA SHEET
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System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SAR - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Vertical lines in the left hand margin indicate an amendment from the previous version.

Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

Sources of key data used to compile the Safety Data Sheet:
The specifications are based on own tests and/or literature data.

Revision Date: 10/13/2017

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / EN