Annora

SAFETY DATA SHEET

Section 1: Identification	
Product **Recommended use**	Fesoterodine Fumarate Extended Release tablets Pharmaceutical product for the treatment of overactive bladder.
Manufacturer	Annora Pharma Private Limited
Distributor	**Camber Pharmaceuticals, Inc.**, Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Hazard statement(s)	Suspected of damaging the unborn
Precautionary Statements	Do not handle until all safety precautions have been read and understood Use personal protective equipment as required IF exposed or concerned: Get medical attention/advice Store locked up Dispose of contents/container in accordance with all local and national regulations
Other Hazards	No data available **Note:** This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.
Section 3: Composition/Information on Ingredients	
Ingredients	Fesoterodine fumarate
CAS	286930-03-8
Section 4: First-Aid Measures	
Inhalation	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Skin Contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Eye Contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately
Section 5: Fire-Fighting Measures	
Extinguishing Media	Extinguish fires with CO2, extinguishing powder, foam, or water.
Special Hazards Arising from the Substance or Mixture Hazardous Combustion Products: **Fire / Explosion Hazards:**	Formation of toxic gases is possible during heating or fire. May include oxides of carbon and nitrogen Not determined
Advice for firefighters	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Section 6: Accidental Release Measures	

Personal Precautions, Protective Equipment and Emergency Procedures	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.
Environmental Precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Methods and Material for Containment and Cleaning Up **Measures for Cleaning /Collecting:**	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.
Section 7: Handling and Storage	
Precautions for safe handling	Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment. Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Conditions for safe storage, including any incompatibilities **Storage Conditions:**	Store as directed by product packaging.
Specific end use(s):	Pharmaceutical drug product
Section 8: Exposure Controls/Personal Protection	
Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.
Personal Protective Equipment	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes	Wear safety glasses or goggles if eye contact is possible
Skin	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations
Respiratory protection	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)
Section 9: Physical and Chemical Properties	
Physical Form	Film-coated tablets
Colour	4 mg: light blue 8 mg are blue
Description	Fesoterodine fumarate extended-release tablets 4 mg are light blue, oval, biconvex, film coated tablets debossed with 'H' on one side and 'F6' on the other side. They are supplied as follows: Bottles of 30 tablets NDC 31722-033-30 Bottles of 90 tablets NDC 31722-033-90

	Fesoterodine fumarate extended-release tablets 8 mg are blue, oval, biconvex, film coated tablets debossed with 'H' on one side and 'F7' on the other side. They are supplied as follows: Bottles of 30 tablets NDC 31722-034-30 Bottles of 90 tablets NDC 31722-034-90
Section 10: Stability and Reactivity	
Chemical stability	Stable under normal conditions of use.
Reactivity	No data available
Section 11: Toxicological Information	
Information on Toxicological Effects **General Information**	The information included in this section describes the potential hazards of the individual ingredients
Short Term	May be harmful if swallowed. May cause eye irritation if tablets are crushed or broken (based on components).
Long Term	Repeat-dose studies in animals have shown a potential to cause adverse effects on liver and the developing foetus
Known Clinical Effects	Adverse effects most commonly reported in clinical use include dry mouth constipation, upset stomach, dry eyes, urinary tract infection, abdominal pain, back pain, inflammation of the pharynx (pharyngitis), painful urination, and difficulty with urination.
Acute Toxicity: (Species, Route, End Point, Dose) **Fesoterodine fumarate** Rat Oral LD50 ~ 681 mg/kg Mouse Oral LD50 ~ 316mg/kg Rat Intravenous NOAEL 10mg/kg Mouse Intravenous NOAEL 10mg/kg	
Section 12: Ecological Information	
Environmental Overview	Environmental properties have not been investigated. Releases to the environment should be avoided. The active ingredient in this formulation may be harmful to aquatic organisms. Long term adverse effects to aquatic organisms are possible
Section 13: Disposal Considerations	
Waste Treatment Methods	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.
Section 14: Transport Information	
The following refers to all modes of transportation unless specified below. Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.	
Section 15: Regulatory Information	
Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture	
Fesoterodine fumarate CERCLA/SARA 313 Emission reporting California Proposition 65 EU EINECS/ELINCS List	 Not Listed Not Listed Not Listed
Glycerol dibehenate CERCLA/SARA 313 Emission reporting California Proposition 65 EU EINECS/ELINCS List	 Not Listed Not Listed Not Listed

Microcrystalline cellulose	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex XVII - Restrictions on Certain	Use restricted. See item 9[f]. powder
Dangerous Substances:	232-674-9
EU EINECS/ELINCS List	
Opadry blue	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
Lactose Monohydrate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	Not Listed
Hydroxypropyl methylcellulose	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	Not Listed
Talc (non-asbestiform)	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	238-877-9
Xylitol	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-788-0

Section 16: Other Information

Issue Date : 16-06-2022

Version : 00

Further information

Revision date: New issue

Revision note: New issue

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose. Annora Pharma Private Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Annora Pharma Private Limited reserves the right to revise this SDS.