

SAFETY DATA SHEET

Section 1: Identification	
Product Information	
Product Name	Tolvaptan Tablets
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
Distributor	Camber Pharmaceuticals, Inc. , Piscatway, NJ 08854
Section 2: Hazard(s) Identification	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Not classified
Classification according to Directive 67/548/EEC or 1999/45/EC	Carc.Cat.3; R40 (Limited evidence of a carcinogenic effect)
Adverse physicochemical, human health and environmental effects	No additional information available
Labelling according to Regulation (EC) No. 1272/2008 [CLP]	
Hazard statements (CLP)	H302 - Harmful if swallowed H312 - Harmful in contact with skin H332 - Harmful if inhaled
Precautionary statements (CLP)	P101 - If medical advice is needed, have product container or label at hand P102 - Keep out of reach of children P103 - Read label before use P201 - Obtain special instructions before use P202 - Do not handle until all safety precautions have been read and understood
EUH phrases	EUH210 - Safety data sheet available on request
Section 3: Composition/Information on Ingredients	
Ingredients	Tolvaptan
CAS	150683-30-0
Section 4: First-Aid Measures	
First-aid measures general	Allow the victim to rest in a well ventilated area. Seek immediate Medical attention. Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
First-aid measures after inhalation	Allow the victim to rest in a well ventilated area. Seek immediate Medical attention. Move exposed subject to fresh air immediately. Give artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek medical attention. Remove to fresh air and keep patient at rest. Seek medical attention immediately.
First-aid measures after skin contact	Immediately wash skin with soap and copious Amounts of water for at least 15 minutes. If Irritation persists seek medical attention. Wash immediately with lots of water-Soap may be used-Do not apply (chemical) neutralizing agents-Take victim to a doctor if irritation persists.
First-aid measures after eye contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately. Rinse immediately with lots of water-Do not apply neutralizing agents-Take victim to an ophthalmologist if irritation persists.
First-aid measures after ingestion	If swallowed, wash out mouth with water, provided Person is conscious. Seek medical advice. Rinse mouth with water-Immediately after ingestion; give lots of water to drink

Section 5: Fire-Fighting Measures	
Suitable Extinguishing Media	Use carbon dioxide, dry chemical
Fire hazard	Flammable with air within explosin limits Indirect fire hazard may be ignited by sparks Gas/vapour spreads at floor level; ignition hazard.
Explosion hazard	Not expected for the product, although the packaging is combustible.
Reactivity	Product is not explosive.
Section 6: Accidental Release Measures	
Protective Precautions, Protective Equipment and Emergency Procedures	Keep upwind-Mark the danger area-Consider evacuation-Seal off low-ling area-Close doors and windows of adjacent premises.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Methods and Material For Containment and Cleaning Up	Wipe up with a damp cloth and place in container for disposal. Clean spill area thoroughly.
Other information	Wash clothing and equipment after handling.
Section 7: Handling and storage	
STORAGE	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
Section 8: Exposure Controls/Personal Protection	
Exposure Controls	
Appropriate 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. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal protection equipment:	
Eye Protection	Safety glasses
Protective Gloves	Compatible chemical-resistant gloves
Other Protective Clothing	Lab coat
Respiratory Equipment	Gas mask with filter type A.
Section 9: Physical and Chemical Properties	
Description	Tolvaptan tablets 15 mg are blue, triangular, bevel edged, biconvex tablets debossed with 'H' on one side and 'T9' on the other side. Blister Pack of 100 (10x10) unit dose tablets (Clear PVC-Alu Peelable) NDC 31722-868-01 Blister Pack of 100 (10x10) unit dose tablets (Alu-Alu) NDC 31722-868-02

Tolvaptan tablets 30 mg are blue, round, bevel edged, biconvex tablets debossed with 'H' on one side and 'T10' on the other side.

Blister Pack of 100 (10x10) unit dose tablets (Clear PVC-Alu Peelable) NDC 31722-869-01

Blister Pack of 100 (10x10) unit dose tablets (Alu-Alu) NDC 31722-869-02

Section 10: Stability and Reactivity

Reactivity:	Product is not explosive.
Chemical stability	Stable under normal conditions of use.
Possibility of hazardous reactions	No additional information available
Conditions to avoid	No additional information available
Incompatible materials	As a precautionary measure. Keep away from strong oxidizers.
Hazardous decomposition products	No additional information available

Section 11: Toxicological Information

Acute toxicity :	Not classified
Skin corrosion/irritation :	Not classified
Serious eye damage/irritation :	Not classified
Respiratory or skin sensitisation :	Not classified
Germ cell mutagenicity :	Not classified
Carcinogenicity :	Not classified
Reproductive toxicity :	Not classified
Specific target organ toxicity (single exposure) :	Not classified
Specific target organ toxicity (repeated exposure):	Not classified
Aspiration hazard :	Not classified

Section 12: Ecological Information

Ecology - general	Soluble in dimethylformamide, sparingly Soluble in benzyl alcohol and methanol.
Ecology - air	Not dangerous for the ozone layer(1999/45/EC).
Other adverse effects	No other effects known.

Section 13: Disposal Considerations

Waste Disposal Method:	
Additional information	Wash clothing and equipment after handling.
Ecology - waste materials	Take up liquid spil into absorbent material-Scoop absorbed substance into closing containers.

Section 14: Transport Information

No dangerous good in sense of transport regulations.

Section 15: Regulatory Information

EU-Regulations:

No Annex XVII restrictions
Contains no REACH candidate substance

National regulations:

No additional information available.

Section 16: Other Information

Issue Date: 17-04-2021

Version: 00

Further information

Revision date: Nil

Revision note: Nil

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