

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material	Tolvaptan Tablets (15 mg, 30 mg, 45 mg, 60 mg and 90 mg)
Manufacturer	Lupin Limited Nagpur - 441108 Maharashtra, India
Manufactured for	Lupin Pharmaceuticals, Inc. Naples, FL 34108 United States.
Use of the Substance/mixture	Pharmaceuticals

Section 2: Hazard(s) Identification

Fire and Explosion	Indirect Fire hazard, avoid contamination with oxidizing agents.
Health	Tolvaptan tablets may cause serious liver injury. Please refer to the product information insert.
Environment	No information is available about the potential of this product to produce adverse environmental effects. Avoid release to the environment.

Section 3: Composition/Information on Ingredients

Name	CAS No.	Name	CAS No.
Tolvaptan	150683-30-0	Methylene Chloride NF	75-09-2
Hydroxy Propyl Cellulose NF	9004-64-2	Dehydrated Alcohol USP	64-17-5
Lactose Monohydrate NF	64044-51-5	Magnesium Stearate NF	557-04-0
Microcrystalline Cellulose NF	9004-34-6	Ferric Oxide (Red Iron)	1309-37-1
Corn Starch NF	9005-25-8	-	-

* The exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: First-Aid Measures

General advice	Allow the victim to rest in a well-ventilated area. Seek immediate medical attention.
Eye contact	Wash out immediately with water. If irritation continues, seek medical attention.
Skin Contact	If skin or hair contact occurs, Flush skin and hair with running water (and soap if available). Seek medical attention if irritation occurs.
Inhalation	Allow the victim to rest. Seek immediate medical attention.
Ingestion	Immediately give a glass of water.
Note to physicians	Treat symptomatically.

Section 5: Fire-Fighting Measures

Fire and Explosion Hazard	Indirect Fire hazard, avoid contamination with oxidizing agents.
Extinguishing Media	Carbon dioxide, dry chemicals, or water.
Special Fire fighting procedure	No special provisions are required beyond normal firefighting equipment such as flame and chemical-resistant clothing and 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. Dispose of contaminated gloves after use in accordance with applicable laws. Wash and dry hands.
Environmental precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Disposal Methods	Dispose of in accordance with local, state, and national regulations.

Section 7: Handling and Storage

Precautions for safe handling:	Do not use tolvaptan tablets for a condition for which it was not prescribed. Keep tolvaptan tablets out of the reach of children.
Storage :	Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F) [see USP Controlled Room Temperature].

Section 8: Exposure Controls/Personal Protection

Personal protective equipment	
Hands	Impervious gloves are recommended.
Eyes	Wear safety glasses.
Skin	Impervious protective clothing/ lab coat.
Respiratory protection	Gas mask with filter.

Section 9: Physical and Chemical Properties

HOW SUPPLIED

Tolvaptan tablets, 15 mg are pink to light pink coloured, capsule shape, mottled tablets debossed with "F05" on one side and "LU" on other side.

Tolvaptan tablets, 30 mg are pink to light pink coloured, round shaped, flat faced bevelled edge mottled tablets debossed with "F06" on one side and "LU" on other side.

Tolvaptan tablets, 45 mg are pink to light pink coloured, octagonal shape, mottled tablets debossed with "LU" on one side and "F07" on other side.

Tolvaptan tablets, 60 mg are pink to light pink coloured, almond shaped, flat faced bevelled edge mottled tablets debossed with "LU" on one side and "F08" on other side.

Tolvaptan tablets, 90 mg are pink to light pink coloured, capsule shaped, biconvex mottled tablets debossed with "LU" on one side and "F09" on other side.

Morning and Afternoon Doses	NDC	
	7-Day Blister Card (Containing 14 Tablets)	28-Day Carton (4 Blister Cards Containing a Total of 56 Tablets)
15 mg and 15 mg	70748-240-11	70748-240-13
30 mg and 15 mg	70748-241-11	70748-241-13
45 mg and 15 mg	70748-242-11	70748-242-13
60 mg and 30 mg	70748-243-11	70748-243-13
90 mg and 30 mg	70748-244-11	70748-244-13

30 Count Bottles	NDC
15 mg	70748-238-06
30 mg	70748-239-06

Section 10: Stability and Reactivity

Reactivity	The product is not explosive. Avoid reaction with oxidizing agents.
Chemical stability	The product is considered stable.
Possibility of hazardous reactions	None known.
Incompatible materials	As a precautionary measure, keep away from strong oxidizers.
Hazardous decomposition products	None known.

Section 11: Toxicological Information

Acute Toxicity	: No data available.
Aspiration Hazard	: No data available.
Skin Corrosion/Skin Irritation	: None anticipated from normal handling of this product.
Respiratory/ Skin Sensitization	: None anticipated from normal handling of this product.
Mutagenicity	: No data available.
Carcinogenicity	: No data available.
Specific Target Organ Toxicity	: No data available.
Reproductive Toxicity	: No data available.

Section 12: Ecological Information

Acute Toxicity	: No data is available.
Persistence and biodegradability	: No data is available.
Bioaccumulation	: No data is available.
Mobility in Soil	: Not determined for product.

Section 13: Disposal Considerations

Waste Disposal	: Dispose of contents/ waste in accordance with local regulations.
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Section 14: Transport Information

IATA/ICAO - Not Regulated
IATA Proper shipping Name : N/A
IATA UN/ID No : N/A
IATA Hazard Class : N/A
IATA Packaging Group : N/A
IATA Label : N/A

IMDG - Not Regulated
IMDG Proper shipping Name : N/A
IMDG UN/ID No : N/A
IMDG Hazard Class : N/A
IMDG Flash Point : N/A
IMDG Label : N/A

DOT - Not Regulated
DOT Proper shipping Name : N/A
DOT UN/ID No : N/A
DOT Hazard Class : N/A
DOT Flash Point : N/A
DOT Packing Group : N/A
DOT Label : N/A

Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

Section 16: Other Information

Other information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. 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.

Lupin shall not be held liable for any damage resulting from handling or from contact with the above product. Lupin reserves the right to revise this SDS.