

# LUPIN LIMITED

## SAFETY DATA SHEET

### Section 1: Identification

#### Section 1, Identification

<b>Material</b>	<b>Tadalafil Tablets, USP</b> <b>2. 5 mg, 5 mg, 10 mg and 20 mg</b>
<b>Manufacturer</b>	<b>Lupin Limited</b> Nagpur 441 108 INDIA
<b>Distributor</b>	Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221

### Section 2: Hazard(s) Identification

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<b>Fire and Explosion</b>	Expected to be non-combustible.
<b>Health</b>	<p>Administration of tadalafil to patients who are using any form of organic nitrate, either regularly and/or intermittently, is contraindicated. In clinical pharmacology studies, tadalafil was shown to potentiate the hypotensive effect of nitrates.</p> <p>Tadalafil is contraindicated in patients with a known serious hypersensitivity to tadalafil or ADCIRCA®. Hypersensitivity reactions have been reported, including Stevens-Johnson syndrome and exfoliative dermatitis.</p> <p>Do not use tadalafil in patients who are using a GC stimulator, such as riociguat. PDE5 inhibitors, including tadalafil, may potentiate the hypotensive effects of GC stimulators.</p>
<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects.

### Section 3: Composition/Information on Ingredients

#### Section 3, Composition/information on ingredients

<b>Ingredients</b>	<b>CAS</b>
Tadalafil USP	171596-29-5

## Section 4: First-Aid Measures

### Section 4, First-aid measures

<b>Ingestion</b>	Flush out mouth with water, consult a physician immediately.
<b>Inhalation</b>	In case of inhalation remove to fresh air and seek medical aid.
<b>Skin Contact</b>	Remove immediately contaminated clothes, wash affected skin with plenty of water.
<b>Eye Contact</b>	In case of contact with eyes rinse thoroughly with plenty of water and get medical advice.

### NOTES TO HEALTH PROFESSIONALS

<b>Medical Treatment</b>	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.
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<b>OVERDOSAGE</b>	Single doses up to 500 mg have been given to healthy subjects, and multiple daily doses up to 100 mg have been given to patients. Adverse events were similar to those seen at lower doses. In cases of overdose, standard supportive measures should be adopted as required. Hemodialysis contributes negligibly to tadalafil elimination.
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## Section 5: Fire-Fighting Measures

### Section 5, Fire-fighting measures

<b>Fire and Explosion Hazards</b>	Assume that this product is capable of sustaining combustion.
<b>Extinguishing Media</b>	Use extinguishing media appropriate to surrounding fire conditions, such as water, fog, spray, dry chemical, regular foam, carbon dioxide.
<b>Special Firefighting Procedures</b>	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.
<b>Hazardous Combustion Products</b>	Hazardous combustion or decomposition products are expected when the product is exposed to fire.

## Section 6: Accidental Release Measures

### Section 6, Accidental release measures

<b>Personal Precautions</b>	Avoid excessive contact and contact with eyes. Wear safety goggles or shield.
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**Environmental Precautions**

For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

**Clean-up Methods**

This material is not known to possess additional hazards when spilled beyond those of other non-hazardous solids.

## Section 7: Handling and Storage

**Section 7, Handling and storage****Handling**

No special control measures required for the normal handling of this product.

**Storage**

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Keep out of reach of children.

## Section 8: Exposure Controls/Personal Protection

**Section 8, Exposure controls/personal protection**

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

## Section 9: Physical and Chemical Properties

**Section 9, Physical and chemical properties****Physical Form**

Tadalafil tablets, USP are supplied as follows:

Four strengths of round-shaped tablets are available in different sizes and different shades of yellow, and supplied in the following package sizes:

**2.5 mg:** Light Yellow, round shaped, biconvex film coated tablets, debossed with 'LU' on one side and 'T26' on the other side.

Bottles of 30 Tablets

NDC 68180-919-06

**5 mg:** Yellow colored, round shaped, biconvex film coated tablets debossed with 'LU' on one side and 'T27' on the other side.

Bottles of 30 Tablets

NDC 68180-920-06

**10 mg:** Yellow colored, round shaped, biconvex film coated tablets debossed with 'LU' on one side and 'T28' on the other side.

Bottles of 30 Tablets

NDC 68180-921-06

**20 mg:** Yellow colored, round shaped, biconvex film coated tablets debossed with 'LU' on one side and 'T29' on the other side.

Bottles of 30 Tablets

NDC 68180-922-06

## Section 10: Stability and Reactivity

### Section 10, Stability and reactivity

Stable under recommended storage conditions.

## Section 11: Toxicological Information

### Section 11, Toxicological information

#### Carcinogenesis, Mutagenesis, Impairment of Fertility

Tadalafil was not carcinogenic to rats or mice when administered daily for 2 years at doses up to 400 mg/kg/day. Systemic drug exposures, as measured by AUC of unbound tadalafil, were approximately 10-fold for mice, and 14- and 26-fold for male and female rats, respectively, the exposures in human males given Maximum Recommended Human Dose (MRHD) of 20 mg.

Tadalafil was not mutagenic in the *in vitro* bacterial Ames assays or the forward mutation test in mouse lymphoma cells. Tadalafil was not clastogenic in the *in vitro* chromosomal aberration test in human lymphocytes or the *in vivo* rat micronucleus assays.

There were no effects on fertility, reproductive performance or reproductive organ morphology in male or female rats given oral doses of tadalafil up to 400 mg/kg/day, a dose producing AUCs for unbound tadalafil of 14-fold for males or 26-fold for females the exposures observed in human males given the MRHD of 20 mg. In beagle dogs given tadalafil daily for 3 to 12 months, there was treatment-related non-reversible degeneration and atrophy of the seminiferous tubular epithelium in the testes in 20 to 100% of the dogs that resulted in a decrease in spermatogenesis in 40 to 75% of the dogs at doses of  $\geq 10$  mg/kg/day. Systemic exposure (based on AUC) at no-observed-adverse-effect-level (NOAEL) (10 mg/kg/day) for unbound tadalafil was similar to that expected in humans at the MRHD of 20 mg.

There were no treatment-related testicular findings in rats or mice treated with doses up to 400 mg/kg/day for 2 years.

## Section 12: Ecological Information

### Section 12: Ecological Information

No relevant studies identified.

## Section 13: Disposal Considerations

### Section 13: Disposal Considerations

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

## Section 14: Transport Information

### 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

### Section 15: Regulatory Information

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

## Section 16: Other Information

### Section 16, 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.