


LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification

Material	Testosterone Topical Solution,  30 mg/1.5 mL
Manufacturer	Lupin Limited Pithampur (M.P.) – 454 775 India
Distributor	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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Fire and Explosion	Expected to be non-combustible.
Health	<ul style="list-style-type: none">• Testosterone topical solution is contraindicated in men with carcinoma of the breast or known or suspected carcinoma of the prostate.• Testosterone topical solution is contraindicated in women who are, or who may become pregnant, or who are breastfeeding. Testosterone topical solution may cause fetal harm when administered to a pregnant woman. Testosterone topical solution may cause serious adverse reactions in nursing infants. If a pregnant woman is exposed to testosterone topical solution, she should be apprised of the potential hazard to the fetus.
Environment	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

Ingredients	CAS
Testosterone	58-22-0

Section 4: First-Aid Measures

Section 4, First-aid measures

Ingestion	Immediately give large quantities of water to drink. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician immediately.
Inhalation	Remove to fresh air. If breathing stops, provide artificial respiration. Get medical attention immediately.
Skin Contact	Wash off immediately with plenty of water. Continue to rinse for at least 15 minutes. Immediately take off all contaminated clothing. Get medical attention if irritation develops and persists.
Eye Contact	In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	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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OVERDOSAGE	No cases of overdose with testosterone topical solution have been reported in clinical trials. There is one report of acute overdosage by injection of testosterone enanthate: testosterone concentrations of up to 11,400 µg/dL were implicated in a cerebrovascular accident. Treatment of overdosage would consist of discontinuation of testosterone topical solution together with appropriate symptomatic and supportive care.
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Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures

Fire and Explosion Hazards	Assume that this product is capable of sustaining combustion.
Extinguishing Media	Water. Carbon dioxide (CO ₂). Dry chemical powder.
Special Firefighting Procedures	Wear self-contained breathing apparatus and protective clothing.
Hazardous Combustion Products	Hazardous combustion or decomposition products are expected when the product is exposed to fire.

Section 6: Accidental Release Measures

Section 6, Accidental release measures

Personal Precautions	Wear suitable protective clothing, gloves and eye/face protection.
Environmental Precautions	Avoid release to the environment.

Clean-up Methods

Use absorbent/adsorbent material to solidify liquids. Do not vacuum.
Remove sources of ignition.
Use only non-sparking tools.

Section 7: Handling and Storage

Section 7, Handling and storage**Handling**

Wear personal protective equipment.

Storage

Keep testosterone topical solution out of reach of children.
Store upright at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

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**

Testosterone topical solution is available as a metered-dose pump containing 110 mL of solution. The pump is capable of dispensing 90 mL of solution in 60 metered pump actuations. One actuation delivers 30 mg of testosterone in 1.5 mL of solution. Each metered-dose pump is supplied with an applicator. The bottle and the applicator cup are not made with natural rubber latex.

NDC	Pump Type
68180-943-11	Pump Actuated

Section 10: Stability and Reactivity

Section 10, Stability and reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport.

Section 11: Toxicological Information

Section 11, Toxicological information**Carcinogenesis, Mutagenesis, Impairment of Fertility**

Testosterone has been tested by subcutaneous injection and implantation in mice and rats. In mice, the implant induced cervical-uterine tumors, which metastasized in some cases. There is suggestive evidence that injection of testosterone into some strains of female mice increases their susceptibility to hepatoma. Testosterone is also known

to increase the number of tumors and decrease the degree of differentiation of chemically induced carcinomas of the liver in rats. Testosterone was negative in the *in vitro* Ames and in the *in vivo* mouse micronucleus assays. The administration of exogenous testosterone has been reported to suppress spermatogenesis in the rat, dog and non-human primates, which was reversible on cessation of the treatment.

Section 12: Ecological Information

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No relevant studies identified.

Section 13: Disposal Considerations

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

Section 14: Transport Information

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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

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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.