

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification

Material	Norethindrone Tablets USP 0.35 mg
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	Progestin-only oral contraceptives (POPs) should not be used by women who currently have the following conditions: <ul style="list-style-type: none">• Known or suspected pregnancy• Known or suspected carcinoma of the breast• Undiagnosed abnormal genital bleeding• Hypersensitivity to any component of this product• Benign or malignant liver tumors• Acute liver disease
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
Norethindrone USP	68-22-4

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.
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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	Flush eyes with plenty of water. 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.
OVERDOSAGE	There have been no reports of serious ill effects from overdosage, including ingestion by children.

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 spray, carbon dioxide, dry chemical powder or appropriate foam.
Special Firefighting Procedures	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.
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	Collect and place it in a suitable, properly labeled container for recovery or disposal.

Section 7: Handling and Storage

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Handling	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
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Storage

Store 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**

Norethindrone Tablets USP containing 0.35 mg of norethindrone, are yellow coloured, round flat face beveled edge tablets debossed with "LU" on one side and "J22" on the other side.

Norethindrone Tablets USP are available in a blister (NDC 68180-876-71) containing 28 tablets. Three such blisters are packaged in a carton (NDC 68180-876-73).

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**

Some epidemiologic studies of oral contraceptive users have reported an increased relative risk of developing breast cancer, particularly at a younger age and apparently related to duration of use. These studies have predominantly involved combined oral contraceptives and there is insufficient data to determine whether the use of POPs similarly increase the risk. Women with breast cancer should not use oral contraceptives because the role of female hormone in breast cancer has not been fully determined.

Some studies suggest that oral contraceptive use has been associated with an increase in the risk of cervical intraepithelial neoplasia in some populations of women. However, there continues to be controversy about the extent to which such findings may be due to differences in sexual behavior and other factors. There is insufficient data to determine whether the use of POPs increases the risk of developing cervical intraepithelial neoplasia.

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.