

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification

Material	Tri-Lo-Marzia™ (Norgestimate and Ethinyl Estradiol Tablets USP) 0.180 mg/0.025 mg, 0.215 mg/0.025 mg and 0.250 mg/0.025 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

Section 2, Hazard(s) identification

Fire and Explosion	Expected to be non-combustible.
Health	<p>Do not prescribe Tri-Lo-Marzia to women who are known to have the following conditions:</p> <ul style="list-style-type: none">• A high risk of arterial or venous thrombotic diseases. Examples include women who are known to:<ul style="list-style-type: none">○ Smoke, if over age 35○ Have deep vein thrombosis or pulmonary embolism, now or in the past○ Have inherited or acquired hypercoagulopathies○ Have cerebrovascular disease○ Have coronary artery disease○ Have thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation)○ Have uncontrolled hypertension○ Have diabetes mellitus with vascular disease○ Have headaches with focal neurological symptoms or migraine headaches with aura<ul style="list-style-type: none">▪ Women over age 35 with any migraine headaches• Liver tumors, benign or malignant, or liver disease• Undiagnosed abnormal uterine bleeding• Pregnancy, because there is no reason to use COCs during pregnancy• Breast cancer or other estrogen- or progestin-sensitive cancer, now or in the past• Use of Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to the potential for ALT elevations

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
Ethinyl Estradiol	57-63-6

Section 4: First-Aid Measures

Section 4, First-aid measures

Ingestion	If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention.
Inhalation	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
Skin Contact	Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.
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 of oral contraceptives, including ingestion by children. Overdosage may cause withdrawal bleeding in females and nausea.
-------------------	--

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

Hazardous Combustion Products

apparatus and full protective equipment are recommended for firefighters.

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 protective clothing and equipment consistent with the degree of hazard.

Environmental Precautions

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

Clean-up Methods

Collect and place it in a suitable, properly labeled container for recovery or disposal.

Section 7: Handling and Storage

Section 7, Handling and storage**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.

Storage

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

Protect from light.

Keep this and all medication 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**

Tri-Lo-Marzia are available in a blister (NDC 68180-837-71) containing 28 tablets packed in a pouch (NDC 68180-837-71). Such three pouches are packaged in a carton (NDC 68180-837-73).

Each blister (28 tablets) contains in the following order:

- 7 white to off white, round, film-coated tablets debossed with 'LU' on one side and "E21" on the other side contains 0.18 mg norgestimate and 0.025 mg ethinyl estradiol
- 7 light blue, round, film-coated tablets debossed with 'LU' on one side and "E22" on the other side contains 0.215 mg norgestimate

- and 0.025 mg ethinyl estradiol
- 7 blue, round, film-coated tablets debossed with 'LU' on one side and "E23" on the other side contains 0.25 mg norgestimate and 0.025 mg ethinyl estradiol
- 7 green, round, biconvex, film-coated tablets (non-hormonal placebo) debossed with 'LU' on one side and "E24" on the other side contains inert ingredients

Section 10: Stability and Reactivity

Section 10, Stability and reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Section 11, Toxicological information

Carcinoma of Breast and Cervix

Tri-Lo-Marzia is contraindicated in women who currently have or have had breast cancer because breast cancer may be hormonally sensitive.

There is substantial evidence that COCs do not increase the incidence of breast cancer. Although some past studies have suggested that COCs might increase the incidence of breast cancer, more recent studies have not confirmed such findings.

Some studies suggest that COC use has been associated with an increase in the risk of cervical cancer or intraepithelial neoplasia. However, there continues to be controversy about the extent to which such findings may be due to differences in sexual behavior and other factors.

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.