

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material	Levonorgestrel and Ethinyl Estradiol Tablets USP 0.15 mg/0.03 mg
Manufacturer	Lupin Limited Pithampur (M.P.) – 454 775 INDIA.
Distributor	Lupin Pharmaceuticals, Inc. Naples, FL 34108 United States.

Section 2: Hazard(s) Identification

Fire and Explosion	Expected to be non-combustible.
Health	Oral contraceptives should not be used in women who currently have the following conditions: • Thrombophlebitis or thromboembolic disorders • A past history of deep vein thrombophlebitis or thromboembolic disorders • Cerebrovascular or coronary artery disease (current or history) • Valvular heart disease with thrombogenic complications • Uncontrolled hypertension • Diabetes with vascular involvement • Headaches with focal neurological symptoms • Major surgery with prolonged immobilization • Known or suspected carcinoma of the breast or personal history of breast cancer • Carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia • Undiagnosed abnormal genital bleeding • Cholestatic jaundice of pregnancy or jaundice with prior pill use • Hepatic adenomas or carcinomas, or active liver disease • Known or suspected pregnancy • Hypersensitivity to any component of this product
Environment	No information is available about the potential of this product to produce adverse environmental effects.

Section 3: Composition/Information on Ingredients

Ingredients	CAS No.	Ingredients	CAS No.
Levonorgestrel USP	797-63-7	Methylene Chloride NF	75-09-2
Ethinyl Estradiol USP	57-63-6	Croscarmellose Sodium NF	74811-65-7
Lactose Anhydrous NF	63-42-3	Magnesium Stearate NF	557-04-0
Microcrystalline Cellulose NF	9004-34-6	Opadry Blue 03B80827	9004-65-3
Povidone USP	9003-39-8	Purified Water USP	7732-18-5

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

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	Serious ill effects have not been reported following acute ingestion of large doses of oral contraceptives by young children. Overdosage may cause nausea, and withdrawal bleeding may occur in females.

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

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

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].

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

Physical Form	HOW SUPPLIED Levonorgestrel and ethinyl estradiol tablets USP, 0.15 mg/0.03 mg are available in Extended Cycle blister card of 91 tablets each containing a 13-week supply of tablets which is packed in a pouch (NDC 68180-843-71). Such three pouches are packed in a carton (NDC 68180-843-73). Each blister card (91 tablets) contains in the following order: • 84 pink, round, biconvex, film-coated tablets, each containing 0.15 mg of levonorgestrel and 0.03 mg ethinyl estradiol; debossed with LU on one side and U21 on the other side • 7 white to off white, round, biconvex, inert tablets debossed with LU on one side and U22 on the other side.
----------------------	---

Section 10: Stability and Reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Carcinoma of the Reproductive Organs and Breasts

Numerous epidemiological studies have been performed on the incidence of breast, endometrial, ovarian and cervical cancer in women using oral contraceptives. Although the risk of having breast cancer diagnosed may be slightly increased among current and recent users of combined oral contraceptives (RR=1.24), this excess risk decreases over time after combination oral contraceptive discontinuation and by 10 years after cessation the increased risk disappears. The risk does not increase with duration of use and no consistent relationships have been found with dose or type of steroid. The patterns of risk are also similar regardless of a woman's reproductive history or her family breast cancer history. The subgroup for whom risk has been found to be significantly elevated is women who first used oral contraceptives before age 20, but because breast cancer is so rare at these young ages, the number of cases attributable to this early oral contraceptive use is extremely small. Breast cancers diagnosed in current or previous oral contraceptive users tend to be less clinically advanced than in never-users. Women who currently have or have had breast cancer should not use oral contraceptives because breast cancer is a hormone sensitive tumor.

Some studies suggest that oral contraceptive use has been associated with an increase in the risk of cervical intraepithelial neoplasia or invasive cervical cancer 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. In spite of many studies of the relationship between oral contraceptive use and breast cancer and cervical cancers, a cause-and-effect relationship has not been established.

Section 12: Ecological Information

No relevant studies identified.

Section 13: Disposal Considerations

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

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

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.