# Safety Data Sheet

## Section 1: Identification

<table>
<thead>
<tr>
<th>Material</th>
<th>Levonorgestrel and Ethinyl Estradiol Tablets USP 0.15 mg/0.03 mg</th>
</tr>
</thead>
</table>
| 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

### 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**

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<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS</th>
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<tbody>
<tr>
<td>Levonorgestrel USP</td>
<td>797-63-7</td>
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<tr>
<td>Ethinyl Estradiol USP</td>
<td>57-63-6</td>
</tr>
</tbody>
</table>

**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. 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**

**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...
<table>
<thead>
<tr>
<th>Hazardous Combustion Products</th>
<th>this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hazardous combustion or decomposition products are expected when the product is exposed to fire.</td>
</tr>
</tbody>
</table>

### 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]

### 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**
- **HOW SUPPLIED**
  - Levonor gestrel and Ethinyl Estradiol Tablets USP, 0.15 mg/0.03 mg are available in Extended-Cycle Wallets, each containing a 13-week supply of tablets: 84 pink tablets each containing 0.15 mg Levonor gestrel and 0.03 mg Ethinyl Estradiol, and 7 white to off white inert tablets. Active pink tablets are round biconvex film coated tablets, debossed with “LU” on one side and “U21” on the other side. The inert tablets are white to off white tablets with “LU” on one side and “U22” on the other side.
They are supplied as follows:

Levonorgestrel and Ethinyl Estradiol Tablets USP, 0.15 mg/0.03 mg are available in Extended-Cycle Wallets of 91 tablets which is packed in a pouch (NDC 68180-843-11). Such three pouches are packed in a carton (NDC 68180-843-13).

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 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

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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**

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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.