

# LUPIN LIMITED

## SAFETY DATA SHEET

### Section 1: Identification

#### Section 1, Identification

<b>Material</b>	<b>Vyfemla™</b> <b>(Norethindrone and Ethinyl Estradiol Tablets USP)</b> <b>0.4 mg/0.035 mg</b>
<b>Manufacturer</b>	<b>Lupin Limited</b> Pithampur (M.P.) – 454 775 INDIA.
<b>Distributor</b>	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

<b>Fire and Explosion</b>	Expected to be non-combustible.
<b>Health</b>	Oral contraceptives should not be used in women who currently have the following conditions: <ul style="list-style-type: none"><li>• Thrombophlebitis or thromboembolic disorders</li><li>• A past history of deep vein thrombophlebitis or thromboembolic disorders</li><li>• Cerebrovascular or coronary artery disease</li><li>• Known or suspected carcinoma of the breast</li><li>• Carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia</li><li>• Undiagnosed abnormal genital bleeding</li><li>• Cholestatic jaundice of pregnancy or jaundice with prior pill use</li><li>• Hepatic adenomas or carcinomas</li><li>• Known or suspected pregnancy</li></ul>
<b>Environment</b>	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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<b>Ingredients</b>	<b>CAS</b>
Norethindrone USP	68-22-4
Ethinyl Estradiol USP	57-63-6

## Section 4: First-Aid Measures

### Section 4, First-aid measures

<b>Ingestion</b>	If accidental ingestion occurs, flush mouth out with water and get medical attention.
<b>Inhalation</b>	The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention.
<b>Skin Contact</b>	Wash off immediately with plenty of water. Continue to rinse for at least 15 minutes. Get medical attention if irritation develops and persists.
<b>Eye Contact</b>	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

<b>Medical Treatment</b>	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.
<b>OVERDOSAGE</b>	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

<b>Fire and Explosion Hazards</b>	Assume that this product is capable of sustaining combustion.
<b>Extinguishing Media</b>	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
<b>Special Firefighting Procedures</b>	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.
<b>Hazardous Combustion Products</b>	Hazardous combustion or decomposition products are expected when the product is exposed to fire.

## Section 6: Accidental Release Measures

### Section 6, Accidental release measures

<b>Personal Precautions</b>	Wear suitable protective clothing, gloves and eye/face protection.
<b>Environmental Precautions</b>	Avoid release to the environment.
<b>Clean-up Methods</b>	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

Vyfemla (norethindrone and ethinyl estradiol tablets USP, 0.4 mg/0.035 mg) is available in blister (NDC 68180-875-71) containing 28 tablets packed in a pouch (NDC 68180-875-71). Such three pouches are packaged in a carton (NDC 68180-875-73).

- Each of the 21 light peach colored, round, flat face, beveled edged tablets, debossed with "LU" on one side and "I25" on the other side containing 0.4 mg norethindrone and 0.035 mg ethinyl estradiol.
- Each of the 7 white to off-white, round, biconvex tablets, debossed with "LU" on one side and "U22" on other side containing inert ingredients.

## 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

Numerous epidemiological studies have been performed on the incidence of breast, endometrial, ovarian, and cervical cancer in women using oral contraceptives. The overwhelming evidence in the literature suggests that use of oral contraceptives is not associated with an increase in the risk of developing breast cancer, regardless of the age and parity of first use or with most of the marketed brands and doses. The Cancer and Steroid Hormone (CASH) study also showed no latent effect on the risk of breast cancer for at least a decade following long-term use. A few studies have shown a slightly increased relative risk of developing breast cancer,

although the methodology of these studies, which included differences in examination of users and nonusers and differences in age at start of use, has been questioned.

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.

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

### 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.