

# LUPIN LIMITED

## SAFETY DATA SHEET

### Section 1: Identification

#### Section 1, Identification

<b>Material</b>	<b>AMABELZ™ (Estradiol and Norethindrone Acetate Tablets USP) 1 mg/0.5 mg and 0.5 mg/0.1 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

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<b>Fire and Explosion</b>	Expected to be non-combustible.
<b>Health</b>	Amabelz is contraindicated in women with any of the following conditions: <ul style="list-style-type: none"><li>• Undiagnosed abnormal genital bleeding</li><li>• Known, suspected, or history of breast cancer</li><li>• Known, past or suspected estrogen-dependent neoplasia</li><li>• Active DVT, PE, or history of these conditions</li><li>• Active arterial thromboembolic disease (for example stroke and MI), or a history of these conditions</li><li>• Known anaphylactic reaction or angioedema or hypersensitivity to Amabelz</li><li>• Known liver impairment or disease</li><li>• Known protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders</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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Ingredients	CAS
Norethindrone Acetate USP	51-98-9
Estradiol USP	50-28-2

## Section 4: First-Aid Measures

### Section 4, First-aid measures

<b>Ingestion</b>	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.
<b>Inhalation</b>	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
<b>Skin Contact</b>	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.
<b>Eye Contact</b>	Flush eyes with plenty of water. 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.
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<b>OVERDOSAGE</b>	Overdosage of estrogen plus progestin may cause nausea, vomiting, breast tenderness, abdominal pain, drowsiness and fatigue, and withdrawal bleeding may occur in women. Treatment of overdose consists of discontinuation of Amabelz therapy with institution of appropriate symptomatic care.
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## 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.

**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 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 in a dry place protected from light. 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

Amabelz 1 mg/0.5 mg is a white to off-white, round shaped film-coated tablet debossed with "M54" on one side and "LU" on other side.

Amabelz 1 mg/0.5 mg is available in a wallet (NDC 68180-830-11) containing 28 tablets enclosed in a pouch, such 3 pouches are packed in a carton (NDC 68180-830-13).

Amabelz 0.5 mg/0.1 mg is a white to off-white, round shaped film-coated tablet debossed with "M53" on one side and "LU" on other side.

Amabelz 0.5 mg/0.1 mg is available in a wallet (NDC 68180-829-11) containing 28 tablets enclosed in a pouch, such 3 pouches are packed in a carton (NDC 68180-829-13).

## Section 10: Stability and Reactivity

### Section 10, Stability and reactivity

Stable under recommended storage conditions.

## Section 11: Toxicological Information

### Section 11, Toxicological information

#### Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term continuous administration of natural and synthetic estrogens in certain animal species increases the frequency of carcinomas of the breast, uterus, cervix, vagina, testis, and liver.

## 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.