

# LUPIN LIMITED

## SAFETY DATA SHEET

### Section 1: Identification

|                                     |  |
|-------------------------------------|--|
| <b>Material</b>                     | <b>Turqoz™<br/>(Norgestrel and Ethinyl Estradiol Tablets USP)<br/>0.30 mg/0.03 mg</b>  |
| <b>Manufacturer</b>                 | <b>Lupin Limited</b><br>Pithampur (M.P.) – 454 775<br>INDIA.   |
| <b>Distributor</b>                  | Lupin Pharmaceuticals, Inc.<br>111 South Calvert Street,<br>Harborplace Tower, 21st Floor,<br>Baltimore, Maryland 21202<br>United States<br><br>Tel. 001-410-576-2000<br>Fax. 001-410-576-2221 |
| <b>Use of the Substance/mixture</b> | Pharmaceuticals  |

### 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 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>• Cerebral vascular 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, carcinomas or benign liver tumors</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

#### Composition/information on ingredient:

| Ingredient             | CAS No.    |
|------------------------|------------|
| Norgestrel USP         | 6533-00-2  |
| Ethinyl Estradiol USP  | 57-63-6    |
| Povidone k-30 USP      | 9003-39-8  |
| Methylene Chloride     | 75-09-2    |
| Lactose Monohydrate NF | 10039-26-6 |
| Magnesium Stearate     | 557-04-0   |

\* 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

#### Extinguishing Media

Assume that this product is capable of sustaining combustion.

#### Special Firefighting Procedures

Water spray, carbon dioxide, dry chemical powder or appropriate foam.

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.

Avoid all personal contact, including inhalation.

Wear protective clothing when risk of exposure occurs

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].

Keep this and all medications out of reach of children.

## 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

Turqoz Tablets (norgestrel and ethinyl estradiol tablets USP) 0.30 mg/0.03 mg: Each white to off-white, round shaped, tablets debossed with "LU" on one side and "Z41" on other side contains 0.30 mg norgestrel and 0.03 mg ethinyl estradiol. Turqoz is packaged in 1 wallet and cartons of three wallets. Each wallet contains 21 white (active) tablets and 7 orange (inert) tablets. Inert tablets are orange colored round shaped, tablets debossed with "T22" on one side and "LU" on the other side.

## Section 10: Stability and Reactivity

Stable under recommended storage conditions.

## Section 11: Toxicological Information

### Carcinoma of the Breast and Reproductive Organs

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 non-users and differences in age at start of use, has been questioned. Some studies have reported an increased relative risk of developing breast cancer, particularly at a younger age. This increased relative risk appears to be related to duration of use. 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 or 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.