

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification

Material	Fayosim™ (Levonorgestrel and Ethinyl Estradiol Tablets USP), and Ethinyl Estradiol Tablets USP (0.15 mg/0.02 mg, 0.15 mg/0.025 mg, 0.15 mg/0.03 mg) and 0.01 mg
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

Section 2, Hazard(s) identification

Fire and Explosion	Expected to be non-combustible.
Health	<p>Do not prescribe Fayosim to women who are known to have the following conditions:</p> <ul style="list-style-type: none">• A high risk of arterial or venous thrombotic diseases. Examples include women who are known to:<ul style="list-style-type: none">– Smoke, if over age 35.– Have deep vein thrombosis or pulmonary embolism, now or in the past.– Have cerebrovascular disease.– Have coronary artery disease.– Have thrombogenicvalvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation).– Have inherited or acquired hypercoagulopathies.– Have uncontrolled hypertension.– Have diabetes with vascular disease.– Have headaches with focal neurological symptoms or have migraine headaches with or without aura if over age 35.• Liver tumors, benign or malignant, or liver disease• Undiagnosed abnormal uterine bleeding.• Pregnancy, because there is no reason to use COCs during pregnancy.• Breast cancer or other estrogen- or progestin-sensitive cancer, now or in the past.

Environment

No information is available about the potential of this product to produce adverse environmental effects.

Section 3: Composition/Information on Ingredients

Section 3, Composition/information on ingredients

Ingredients	CAS
Levonorgestrel USP	797-63-7
Ethinyl Estradiol USP	57-63-6

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. 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	There have been no reports of serious ill effects from overdose of oral contraceptives, including ingestion by children. Overdosage may cause withdrawal bleeding in females and nausea.
-------------------	--

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 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 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**

Fayosim™ (levonorgestrel and ethinyl estradiol tablets USP, and ethinyl estradiol tablets USP) are available in Extended-Cycle Wallets each containing a 13-week supply of tablets in the following order:

- 42 pink, round, biconvex film-coated tablets, each containing 0.15 mg of levonorgestrel and 0.02 mg ethinyl estradiol: debossed with "LU" on one side and "U19" on the other side.
- 21 white, round, biconvex film-coated tablets, containing 0.15 mg of levonorgestrel and 0.025 mg ethinyl estradiol: debossed with "LU" on one side and "U20" on the other side.
- 21 light blue, round, biconvex film-coated tablets, containing 0.15 mg of levonorgestrel and 0.03 mg ethinyl estradiol: debossed with "LU" on one side and "V21" on the other side.
- 7 mustard, round, biconvex film-coated tablets, containing 0.01 mg of ethinyl estradiol: debossed with "LU" on one side and debossed with V22 on the other side.

They are supplied as follows:

1 extended cycle wallet of 91 tablets which is packed in a pouch (NDC 68180-860-11). Such one pouch is packed in a carton (NDC 68180-860-12).

2 extended cycle wallets of 91 tablets each which is packed in a pouch (NDC 68180-860-11). Such two pouches are packed in a carton (NDC 68180-860-13).

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

Fayosim™ is contraindicated in women who currently have or have had breast cancer because breast cancer may be hormonally sensitive.

There is substantial evidence that COCs do not increase the incidence of breast cancer. Although some past studies have suggested that COCs might increase the incidence of breast cancer, more recent studies have not confirmed such findings.

Some studies suggest that COCs are associated with an increase in the risk of cervical cancer or intraepithelial neoplasia. However, there is controversy about the extent to which these findings are due to differences in sexual behavior and other factors.

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.