

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

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Material	Fluoxetine Tablets, USP 10 mg and 20 mg
Manufacturer	Lupin Limited Nagpur 441 108 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

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Fire and Explosion	Expected to be non-combustible.
Health	<p>The use of MAOIs intended to treat psychiatric disorders with fluoxetine or within 5 weeks of stopping treatment with fluoxetine is contraindicated because of an increased risk of serotonin syndrome. The use of fluoxetine within 14 days of stopping an MAOI intended to treat psychiatric disorders is also contraindicated.</p> <p>Starting fluoxetine in a patient who is being treated with MAOIs such as linezolid or intravenous methylene blue is also contraindicated because of an increased risk of serotonin syndrome.</p> <p>The use of fluoxetine is contraindicated with the following:</p> <ul style="list-style-type: none">• Pimozide• Thioridazine <p>Pimozide and thioridazine prolong the QT interval. Fluoxetine can increase the levels of pimozide and thioridazine through inhibition of CYP2D6. Fluoxetine can also prolong the QT interval.</p>
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
Fluoxetine Hydrochloride USP	59333-67-4

Section 4: First-Aid Measures

Section 4, First-aid measures

Ingestion	Give several glasses of water. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician or poison control center immediately.
Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. Get medical attention immediately.
Skin Contact	Immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.
Eye Contact	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 immediately.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Fluoxetine Hydrochloride - Cardiac and vital signs monitoring is recommended, along with general symptomatic and supportive measures. No specific antidote is known. Forced diuresis, dialysis, haemoperfusion, and exchange transfusion are unlikely to be of benefit. In limited human overdose experience, seizures have been reported. Appropriate seizure precautions are advised for any patient regularly taking fluoxetine who has been exposed to an acute overdose. Based on experience in animals, which may not be relevant to humans, fluoxetine-induced seizures that fail to remit spontaneously may respond to diazepam.
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OVERDOSAGE

Worldwide exposure to fluoxetine hydrochloride is estimated to be over 38 million patients (circa 1999). Of the 1578 cases of overdose involving fluoxetine hydrochloride, alone or with other drugs, reported from this population, there were 195 deaths.

Among 633 adult patients who overdosed on fluoxetine hydrochloride alone, 34 resulted in a fatal outcome, 378 completely recovered, and 15 patients experienced sequelae after overdose, including abnormal accommodation, abnormal gait, confusion, unresponsiveness, nervousness, pulmonary dysfunction, vertigo, tremor, elevated blood pressure, impotence, movement disorder, and hypomania. The remaining 206 patients had an unknown outcome. The most common signs and symptoms associated with non-fatal overdose were seizures, somnolence, nausea, tachycardia, and vomiting. The largest known ingestion of fluoxetine hydrochloride in adult patients was 8 grams in a patient who took fluoxetine alone and who subsequently recovered. However, in an adult patient who took fluoxetine alone, an ingestion as low as 520 mg has been associated with lethal outcome, but causality has not been established.

Among pediatric patients (ages 3 months to 17 years), there were 156 cases of overdose involving fluoxetine alone or in combination with other drugs. Six patients died, 127 patients completely recovered, 1 patient experienced renal failure, and 22 patients had an unknown outcome. One of the six fatalities was a 9-year-old boy who had a history of OCD, Tourette's syndrome with tics, attention deficit disorder, and fetal

alcohol syndrome. He had been receiving 100 mg of fluoxetine daily for 6 months in addition to clonidine, methylphenidate, and promethazine. Mixed-drug ingestion or other methods of suicide complicated all 6 overdoses in children that resulted in fatalities. The largest ingestion in pediatric patients was 3 grams which was nonlethal.

Other important adverse reactions reported with fluoxetine overdose (single or multiple drugs) include coma, delirium, ECG abnormalities (such as nodal rhythm, QT interval prolongation and ventricular arrhythmias, including Torsades de Pointes-type arrhythmias), hypotension, mania, neuroleptic malignant syndrome-like reactions, pyrexia, stupor, and syncope.

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures

Fire and Explosion Hazards	Water. Carbon dioxide (CO2). Dry chemical.
Extinguishing Media	Use extinguishing media appropriate to surrounding fire conditions, such as water, fog, spray, dry chemical, regular foam, carbon dioxide.
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 suitable protective clothing, gloves and eye/face protection. Do not breathe dust.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Section 7: Handling and Storage

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Handling	Avoid contact with eyes, skin, and clothing. Wear personal protective equipment.
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Storage

Store at 20°C to 25°C (68° to 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**

Fluoxetine Tablets, USP are available containing fluoxetine hydrochloride, USP equivalent to 10 mg or 20 mg of fluoxetine.

The 10 mg tablets are white to off-white film-coated, oval shaped tablet, debossed with "L" on the left of the score and "U" on the right of the score on one side of the tablet and "F" on the left of the score and "55" on the right of the score on other side. They are available as follows:

NDC 68180-998-06 bottles of 30 tablets
NDC 68180-998-01 bottles of 100 tablets

The 20 mg tablets are white to off-white film-coated, oval shaped tablet, debossed with "L" on the left of the score and "U" on the right of the score on one side of the tablet and "F" on the left of the score and "56" on the right of the score on other side. They are available as follows:

NDC 68180-999-06 bottles of 30 tablets
NDC 68180-999-01 bottles of 100 tablets

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**

The dietary administration of fluoxetine to rats and mice for 2 years at doses of up to 10 mg/kg/day and 12 mg/kg/day, respectively [approximately 1.2 and 0.7 times, respectively, the maximum recommended human dose (MRHD) of 80 mg on a mg/m² basis], produced no evidence of carcinogenicity.

Fluoxetine and norfluoxetine have been shown to have no genotoxic effects based on the following assays: bacterial mutation assay, DNA repair assay in cultured rat hepatocytes, mouse lymphoma assay, and *in vivo* sister chromatid exchange assay in Chinese hamster bone marrow cells.

Two fertility studies conducted in adult rats at doses of up to 7.5 mg/kg/day and 12.5 mg/kg/day (approximately 0.9 and 1.5 times the MRHD on a mg/m² basis) indicated that fluoxetine had no adverse effects on fertility. However, adverse effects on fertility were seen when juvenile rats were treated with fluoxetine.

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

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

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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.