SAFETY DATA SHEET (SDS)

Paroxetine Hydrochloride Extended Release Tablets, USP 12.5 mg, 25 mg, and 37.5 mg

Revision Date: 01-November-2022 Version 2.0

1. IDENTIFICATION

Product Name: Paroxetine Hydrochloride Extended Release Tablets, USP 12.5 mg, 25 mg and 37.5 mg

Product Information: Paroxetine Hydrochloride Extended Release Tablets, USP

Company Name: Cadila Pharmaceuticals Limited

Address: 1389, Dholka – 382225, District: Ahmedabad, Gujarat State, India.

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2. HAZARD(S) IDENTIFICATION

GHS Classification: Exempt from requirements - product regulated as a medicinal product.

Label elements: Exempt from requirements - product regulated as a medicinal product.

Health: The use of MAOIs intended to treat psychiatric disorders with paroxetine extended-release tablets or within 14 days of stopping treatment with paroxetine extended-release tablets is contraindicated because of an increased risk of serotonin syndrome. The use of paroxetine extended-release tablets within 14 days of stopping an MAOI intended to treat psychiatric disorders is also contraindicated.

Starting paroxetine extended-release tablets 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.

Concomitant use with thioridazine is contraindicated.

Concomitant use in patients taking pimozide is contraindicated.

Paroxetine extended-release tablets are contraindicated in patients with a hypersensitivity to paroxetine or to any of the inactive ingredients in paroxetine extended-release tablets.

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name: (3S,4R)-3-[(1,3-benzodioxol-5-yloxy)methyl]-4-(4-fluorophenyl) piperidine hydrochloride hemihydrate.

Product Code: Not applicable

Hazardous Ingredients / Components: Not Applicable

CAS No.: 110429-35-1

Other Components:

Inactive Ingredients	Exposure Limit	CAS No.
Hypromellose	Not Found	9004-65-3
Polyvinyl pyrrolidone	Not Found	9003-39-8
Lactose monohydrate	Not Found	10039-26-6
Magnesium stearate	Not Found	557-04-0
Silicon Dioxide	Not Found	14808-60-7
Glyceryl Behenate	Not Found	77538-19-3
Methacrylic acid and ethyl acrylate copolymer	Not Found	25212-88-8
Sodium lauryl sulfate	Not Found	151-21-3
Polysorbate 80	Not Found	9005-65-6
Talc	Not Found	14807-96-6
Triethyl Citrate	Not Found	77-93-0
Titanium dioxide	Not Found	13463-67-7
Polyethylene glycols	Not Found	25322-68-3
Yellow ferric oxide	Not Found	1309-33-7
D&C Red	Not Found	5858-81-1
FD&C Yellow	Not Found	2783-94-0
FD&C Blue	Not Found	860-22-0

4. FIRST – AID MEASURES

Eye contact: Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Skin contact: Wash off with soap and plenty of water. Consult a physician.

Inhalation: If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

Ingestion: Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

Most important symptoms and effects, both acute and delayed- The following adverse effects have been noted with therapeutic use of this material: nausea; diarrhea; constipation; dry mouth; drowsiness; dizziness; weakness; insomnia; sexual dysfunction; tremor; palpitations.

Indication of any immediate medical attention and special treatment needed- No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.

General information: Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing media: Water. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable Extinguishing media: None known.

Specific hazards arising from the chemical: Emits toxic fumes under fire conditions. Carbon oxides, nitrogen oxides (NOx), Hydrogen chloride gas, Hydrogen fluoride.

Special protective equipment and precautions for firefighters: Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire-fighting equipment /instructions: In the event of fire, cool tanks with water spray.

Specific methods: Cool containers exposed to flames with water until well after the fire is out.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation.

Local authorities should be advised if significant spillages cannot be contained.

Environmental precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.

Clean-up Methods: Collect and place it in a suitable, properly labeled container for recovery or disposal.

7. HANDLING AND STORAGE

Handling: Do not get this material in contact with eyes. Avoid contact with eyes, skin, and clothing. Do not taste or swallow. When using, do not eat, drink or smoke. Avoid release to the environment. Avoid prolonged exposure. Wash hands thoroughly after handling.

Storage: Store at or below 20°C to 25°C (68°F to 77°F) excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

- **EXPOSURE CONTROLS:**

- **Engineering Controls (Ventilation etc.):** Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

➢ **PERSONAL PROTECTION EQUIPMENT:**

- **Eye Protection:** Safety glasses
- **Protective Gloves:** Compatible chemical-resistant gloves
- **Other Protective Clothing:** Lab coat
- **Respiratory Equipment (Specify Type):** NIOSH approved respirator, as conditions warrant.
- **Work/Hygienic/Maintenance Practices:** Facilities storing or utilizing this material should be equipped with an eyewash and a safety shower. Wash thoroughly after handling**.**

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:

Paroxetine Hydrochloride Extended -Release Tablets, USP 12.5 mg

Yellow, biconvex, enteric film-coated, extended release, round tablets debossed with “X1”on one side and plain on the other side. The tablets should be free from all physical defects.

Paroxetine Hydrochloride Extended -Release Tablets, USP 25 mg

Pink, biconvex, enteric film-coated, extended release, round tablets debossed with “X2”on one side and plain on the other side. The tablets should be free from all physical defects.

Paroxetine Hydrochloride Extended -Release Tablets, USP 37.5 mg

Blue, biconvex, enteric film-coated, extended release, round tablets debossed with “X3”on one side and plain on the other side. The tablets should be free from all physical defects.

Odour:	Not available
Odour threshold:	Not available
pH (Value):	Not applicable

Boiling Point:	Not applicable
Melting Point:	Not applicable
Flash point	Not available
Evaporation rate:	Not applicable
Flammability (solid, gas):	Not available
Flammability limits in air	Not applicable
Flammability limit – upper (%):	Not available
Flammability limit – lower (%):	Not applicable
Explosive limit – lower (%):	Not available
Explosive limit – upper (%):	Not applicable
Vapour pressure:	Not applicable
Vapour density	Not available
Specific gravity	Not applicable
Water solubility	Not available
Solubility in other solvents	Not applicable
Solubility (Water):	Not applicable
Solubility (Other):	Not available
Partition Coefficient: (n-octanol/water)	Not applicable
Auto-ignition temperature:	Not available
Decomposition temperature:	Not applicable
Viscosity:	Not available

10. STABILITY AND REACTIVITY

Reactivity: The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability: Stable under recommended storage conditions.

Possibility of hazardous reaction: No dangerous reaction known under conditions of normal use.

Conditions to avoid: Contact with incompatible materials.

Incompatible material: Strong oxidizing agents

Hazardous decomposition products: Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. TOXICOLOGY INFORMATION

Toxicological Effects:

The toxicological effects of this product have not been thoroughly studied.

Paroxetine (hydrochloride) - Toxicity Data: Oral TDLO (woman): 7400 µg/kg/14D (intermittent); Oral TDLO (man): 625 µg/kg; Oral LD50 (rat): 415 mg/kg; Oral LD50 (mouse): 378 mg/kg; Intraperitoneal TDLO (mouse): 4 mg/kg; Subcutaneous TDLO (mouse): 0.03 mg/kg; Oral TDLO (rat): 10 mg/kg;

Chronic Effects on Humans: Paroxetine (hydrochloride) - Investigated as a drug and reproductive effector. Only select Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information

12. ECOLOGICAL INFORMATION

Toxicity: Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.

Persistence and Degradability: No data available.

Bio accumulative Potential: No data available.

Mobility in Soil: No data available.

Results of PBT and vPvB assessment: No data available.

Other adverse effects: No data available.

13. DISPOSAL CONSIDERATIONS

Disposal instructions: Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/ container in accordance with local/regional/national/ international regulations.

Local disposal regulations: Dispose in accordance with all applicable regulations.

Hazardous waste code: The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products: Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

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

15. REGULATORY INFORMATION

Generic Medicine. Approved by USFDA on August 27, 2021 and the ANDA Number is 212645.

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.

Cadila Pharmaceutical Limited shall not be held liable for any damage resulting from handling or from contact with the above product.

Cadila Pharmaceutical Limited reserves the right to revise this SDS.