Safety Data Sheet
Paroxetine Tablets, USP

Strength: 10/20/30/40 mg **Pack Size**: 30/90/100/500 Tablets per bottle **Revision No.:** 02

EMERGENCY OVERVIEW

Each Paroxetine Tablets, USP intended for oral administration contains Paroxetine and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

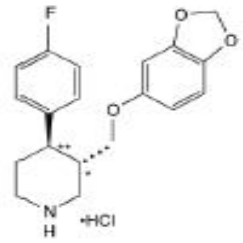
Section 1. Identification

Identification of the product

Product name: Paroxetine Tablets, USP

Formula: $C_{19}H_{20}FNO_3 \cdot HCl \cdot 1/2H_2O$

Chemical Name: (-)-trans-4R-(4'-fluorophenyl)-3S-[(3',4'-methylenedioxyphenoxy) methyl] piperidine hydrochloride hemihydrate



Manufacturer / supplier identification

Company: **Cadila Healthcare Ltd. Ahmedabad, India**

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Recommended use / Therapeutic Category Psychotropic drug

Restriction on Use / Contraindications: Concomitant use in patients taking either monoamine oxidase inhibitors (MAOIs) or thioridazine is contraindicated.

Concomitant use in-patients taking pimozide is contraindicated .

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

Section 2. Hazard(s) Information

Dose and Administration

Major Depressive Disorder:
The recommended initial dose is 20 mg/day. Patients were dosed in a range of 20 to 50 mg/day in the clinical trials demonstrating the effectiveness of paroxetine tablets in the treatment of major depressive disorder.

Obsessive Compulsive Disorder:

The recommended dose of paroxetine tablets in the treatment of OCD is 20- 40 mg daily increased in 10-mg/day increments.The maximum dosage should not exceed 60 mg/day.

Panic Disorder:

The target dose of Paroxetine tablets in the treatment of panic disorder is 10-40 mg/day. Patients should be started on 10 mg/day.The maximum dosage should not exceed 60 mg/day.

Social Anxiety Disorder:

The recommended and initial dosage is 20 mg/day. In clinical trials the effectiveness of paroxetine tablets was demonstrated in patients dosed in a range of 20 to 60 mg/day.

Generalized Anxiety Disorder:

In clinical trials the effectiveness of paroxetine tablets was demonstrated in patients dosed in a range of 20 to 50 mg/day.

Adverse Effects

Major Depressive Disorder:
The most commonly observed adverse events associated are Asthenia, sweating, nausea, decreased appetite, somnolence, dizziness, insomnia, tremor, nervousness, ejaculatory disturbance, and other male genital disorders.

Obsessive Compulsive Disorder:
The most commonly observed adverse events are Nausea, dry mouth, decreased appetite, constipation, dizziness, somnolence, tremor, sweating, impotence, and abnormal ejaculation.

Panic Disorder:
The most commonly observed adverse events are Asthenia, sweating, decreased appetite, libido decreased, tremor, abnormal ejaculation, female genital disorders, and impotence.

Social Anxiety Disorder:
The most commonly observed adverse events are Sweating, nausea, dry mouth, constipation, decreased appetite, somnolence, tremor, libido decreased, yawn, abnormal ejaculation, female genital disorders, and impotence.

Generalized Anxiety Disorder:
The most commonly observed adverse events are Asthenia, infection, constipation, decreased appetite, dry mouth, nausea, libido decreased, somnolence,tremor, sweating, and abnormal ejaculation.

Over Dose Effect

Commonly reported adverse events associated with paroxetine overdosage include somnolence, coma, nausea, tremor, tachycardia, confusion, vomiting, and dizziness. Other notable signs and symptoms observed with overdoses involving paroxetine (alone or with other substances) include mydriasis, convulsions (including status epilepticus), ventricular dysrhythmias (including torsade de pointes), hypertension, aggressive reactions, syncope, hypotension, stupor, bradycardia, dystonia, rhabdomyolysis, symptoms of hepatic dysfunction (including hepatic failure, hepatic necrosis, jaundice, hepatitis, and hepatic steatosis), serotonin syndrome, manic reactions, myoclonus, acute renal failure, and urinary retention.

Medical Conditions

All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.

The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania, have been reported in adult and pediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and nonpsychiatric. Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, there is concern that such symptoms may represent precursors to emerging suicidality.

	Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms. If the decision has been made to discontinue treatment, medication should be tapered, as rapidly as is feasible, but with recognition that abrupt discontinuation can be associated with certain symptoms
Contraindications	Concomitant use in patients taking either monoamine oxidase inhibitors (MAOIs) or thioridazine is contraindicated. Concomitant use in-patients taking pimozide is contraindicated . Paroxetine tablets are contraindicated in patients with a hypersensitivity to paroxetine or any of the inactive ingredients in paroxetine tablets.
Pregnancy Comments	Epidemiological studies have shown that infants born to women Who had first trimester paroxetine exposure had an increased risk of cardiovascular malformations, primarily ventricular and atrial septal defects (VSDs and ASDs). If a patient becomes pregnant while taking paroxetine, she should be advised of the potential harm to the fetus.
Pregnancy Category	D

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component :		
Paroxetine Hydrochloride Hemihydrate equivalent to 10 mg or 20 mg or 30 mg or 40 mg of paroxetine	Not Found	78246-49-8
Inactive Ingredients		
Dibasic calcium phosphate anhydrous	Not Found	7789-77-7
Hypromellose 6 cP	Not Found	9004-65-3
Lactose anhydrous	Not Found	63-42-3

Magnesium stearate	Not Found	557-04-0
Polyethylene glycol 6000	Not Found	25322-68-3
Povidone	Not Found	9003-39-8
Sodium starch glycolate	Not Found	9063-38-1
Talc	Not Found	14807-96-6
Titanium dioxide	Not Found	13463-67-7

Section 4. First - aid measures

General Remove from exposure. Remove contaminated Clothing. Person developing serious hypersensitivity reaction must receive medical attention.

Overdose Treatment Ensure an adequate airway, oxygenation, and ventilation. Monitor cardiac rhythm and vital signs. General supportive and symptomatic measures are also recommended. Induction of emesis is not recommended. Gastric lavage with a large-bore orogastric tube with appropriate airway protection, if needed, may be indicated if performed soon after ingestion, or in symptomatic patients.

Activated charcoal should be administered. Due to the large volume of distribution of this drug, forced diuresis, dialysis, hemoperfusion, and exchange transfusion are unlikely to be of benefit. No specific antidotes for paroxetine are known.

Section 5. Fire - fighting measures

Flash point	Not Found	**Upper Flammable Limit:**	Not Found
Auto-Ignition Temperature:	Not Found	**Lower Flammable Limit:**	Not Found
Extinguishing Media	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.	**Fire and Explosion Hazard**	This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to

dissipate the potential build-up of static electricity.

Fire Fighting Procedure	As with all fires, evacuate personnel to a safe area. Fire fighter should use self- contained breathing equipment and protective clothing.

Section 6. Accidental Release Measures

Spill Response	Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

Section 7. Handling and Storage

Storage	Store at 20° to 25°C (68° to 77°F).
Incompatibilities:	No data available.

Section 8. Exposure controls / personal protection

Respiratory Protection	Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.
Skin Protection	Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.
Eye protection	Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.
Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.
Engineering Control	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Section 9. Physical and chemical properties

Appearance	Paroxetine Tablets USP, 10 mg are white to off-white, round-shaped, biconvex, film- coated tablets debossed with the logo of 'ZC, 15 and bisect' on one side and plain on other side. Paroxetine Tablets USP, 20 mg are white to off-white, round-shaped, biconvex, film- coated tablets debossed with the logo of 'ZC, 16 and bisect' on one side and plain on other side.

Paroxetine Tablets USP, 30 mg are white to off-white, round-shaped, biconvex, film- coated tablets debossed with the logo of 'ZC17' on one side and plain on other side.

Paroxetine Tablets USP, 40 mg are white to off-white, round-shaped, biconvex, film- coated tablets debossed with the logo of 'ZC18' on one side and plain on other side.

Solubility in water	No Data Available	**Odour**	Odourless
Boiling point	No Data Available	**Melting Point**	No Data Available
Evaporation rate	No Data Available	**Vapour density**	No Data Available
Reactivity in water	No Data Available	**Evaporation rate**	No Data Available
% Volatile by volume	No Data Available	**Specific gravity**	No Data Available
		Vapour pressure	No Data Available

Other information Paroxetine hydrochloride hemihydrate is an odorless, white to off-white crystalline powder, having a melting point range of 120° to 138°C. It is freely soluble in methanol, soluble in ethanol, sparingly soluble in dichloromethane and slightly soluble in water.

Section 10. Stability and Reactivity

Condition to avoid	Avoid exposure to extreme heat, light and moisture.	**Stable**	Stable under normal ambient and anticipated storage and handling conditions.
Decomposition Products	No Data Available	**Hazardous Reaction**	No data available.
Incompatibilities:	No data available.		

Section 11. Toxicological information

General	Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.
Target organ	Eye contact, Skin contact and inhalation is not great risk as this product is tablet.
Other	Not Applicable

Section 12. Ecological information

Do not allow product to enter drinking water supplies, waste water or soil

Section 13. Disposal Consideration

Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).

Section 15. Regulatory Information

Generic Medicine. Approved by USFDA & the ANDA Number is 077584

Section 16. Other information

None

Date of issue: 28/05/2015 **Supersedes edition of:** 01

The information contained herein is based on the state of our knowledge. It Characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.