Material Safety data sheet
Paroxetine Tablets, USP

Strength: 10/20/30/40 mg. Pack Size: 30/90/100/500 Tablets per bottle
Revision No.: 00

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**EMERGENCY OVERVIEW**
Paroxetine Tablets, USP contain Paroxetine Hydrochloride Hemihydrate and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

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**Section 1. Identification of the substance**

**Identification of the product**

Product name: Paroxetine Tablets, USP
Formula: C₁₉H₂₀FNO₃•HCl•1/2H₂O
Chemical Name: (-)-trans-4R-(4’-fluorophenyl)-3S-[(3’,4’-methylenedioxyphenoxy)methyl] piperidine hydrochloride hemihydrate
Therapeutic Category: Psychotropic drug

**Manufacturer / supplier identification**

Company: Cadila Healthcare Ltd. Ahmedabad, India
Contact for information: Tel.: +91 79 6868100 Fax: +91 79 3750319
Emergency telephone No. Tel.: +91 79 6868100

**Section 2. Composition / information on ingredients**

<table>
<thead>
<tr>
<th>Component</th>
<th>Exposure Limit</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Principle Component:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paroxetine Hydrochloride Hemihydrate equivalent to 10 mg or 20 mg or 30 mg or 40 mg of paroxetine</td>
<td>Not Found</td>
<td>78246-49-8</td>
</tr>
<tr>
<td><strong>Inactive Ingredients:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dibasic calcium phosphate anhydrous</td>
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<td>7789-77-7</td>
</tr>
<tr>
<td>Hypermellose 6 cP</td>
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<td>9004-65-3</td>
</tr>
<tr>
<td>Lactose anhydrous</td>
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<td>63-42-3</td>
</tr>
<tr>
<td>Magnesium stearate</td>
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<td>557-04-0</td>
</tr>
<tr>
<td>Polyethylene glycol 6000</td>
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<td>25322-68-3</td>
</tr>
<tr>
<td>Povidone</td>
<td>Not Found</td>
<td>9003-39-8</td>
</tr>
<tr>
<td>Sodium starch glycolate</td>
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<td>9063-38-1</td>
</tr>
<tr>
<td>Talc</td>
<td>Not Found</td>
<td>14807-96-6</td>
</tr>
<tr>
<td>titanium dioxide</td>
<td>Not Found</td>
<td>13463-67-7</td>
</tr>
</tbody>
</table>
#### Section 3. Health Hazards 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.

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 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

<table>
<thead>
<tr>
<th>Flash point</th>
<th>Not Found</th>
<th>Upper Flammable Limit:</th>
<th>Not Found</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auto-Ignition Temperature:</td>
<td>Not Found</td>
<td>Lower Flammable Limit:</td>
<td>Not Found</td>
</tr>
<tr>
<td>Extinguishing Media</td>
<td>Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.</td>
<td>Fire and Explosion Hazard</td>
<td>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.</td>
</tr>
</tbody>
</table>

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

Section 6. Storage / Spill / Disposal Measures

Storage: Store at 20° to 25° C (68° to 77° F)

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.

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

Section 7. Exposure controls and 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.
Section 8. 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

Percentage
No Data Available

Volatile by volume
No Data Available

Vapour pressure
No Data Available

Specific gravity
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 9. Physical Hazards

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 10. 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 11. Ecological information

No data available on Ecotoxicity

Section 12. Other information

None

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.