

Material Safety Data Sheet:

ROPINIROLE HCL TABLETS

Strength: 0.25,0.5,1,2,3,4,5 mg

Pack Size: 100/1000 tablets per bottle

Revision No: 00

EMERGENCY OVERVIEW

ROPINIROLE HCL contains Ropinirole and excipients considered nontoxic and nonhazardous in small quantities and under conditions of normal occupational exposure.

Section 1. Identification of the substance

Identification of the product

Product name:	Ropinirole HCL Tablets
Formula:	C ₁₆ H ₂₄ N ₂ O•HCl
Chemical Name:	4-[2-(dipropylamino)ethyl]-1,3-dihydro-2H-indol-2-one monohydrochloride
Therapeutic Category	A non-ergoline dopamine agonist with high relative <i>in vitro</i> specificity and full intrinsic activity at the D ₂ and D ₃ dopamine receptor subtypes, binding with higher affinity to D ₃ than to D ₂ or D ₄ receptor subtypes.

Manufacturer / supplier identification

Company:	Cadila Healthcare Ltd. Ahmedabad, India
Contact for information:	Tel.: +91-2717-250331/32/36/37 Fax: +91-2717-250319
Emergency telephone No.	Tel.: +91 79 26868100

Section 2. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component :		
Ropinirole HCL.	Not Found	91374-20-8
Inactive Ingredients :		
Crosscarmellose sodium	Not Found	74811-65-7
Hypromellose	Not Found	9004-65-3
Lactose Monohydrate	Not Found	64044-51-5
Magnesium Stearate	Not Found	557-04-0
Microcrystalline Cellulose	Not Found	9004-34-6
Polyethylene Glycol	Not Found	25322-68-3
Titanium Dioxide	Not Found	13463-67-7

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Section 3. Health Hazards Information

Dose and Administration	<p>Dosing for Parkinson's Disease: DOSAGE MUST BE INDIVIDUALIZED. It is recommended that ropinirole HCL tablets be started at 0.25 mg 3 times daily. Based on individual patient response, dosage should then be titrated with weekly increments.</p> <p>Dosing for Restless Legs Syndrome: The recommended starting dose of ropinirole HCL tablets is 0.25 mg once daily, 1 to 3 hours before bedtime. After 2 days, the dosage can be increased to 0.5 mg once daily and to 1 mg once daily at the end of the first week of dosing.</p>
Adverse Effects	<p>nausea, dizziness, somnolence, headache, vomiting, syncope, fatigue, dyspepsia, viral infection, constipation, pain, increased sweating, asthenia, dependent/leg edema, orthostatic symptoms, abdominal pain, pharyngitis, confusion, hallucinations, urinary tract infections, and abnormal vision.</p>
Over Dose Effect	<p>Overdosage may cause nausea, dizziness, visual hallucinations, hyperhidrosis, claustrophobia, chorea, palpitations, asthenia, and nightmares. Additional symptoms reported for doses of 24 mg or less or for overdoses of unknown amount included vomiting, increased coughing, fatigue, syncope, vasovagal syncope, dyskinesia, agitation, chest pain, orthostatic hypotension, somnolence, and confusional state.</p>
Medical Conditions	<p>Parkinson's Disease: The precise mechanism of action of ropinirole hydrochloride as a treatment for Parkinson's disease is unknown, although it is believed to be due to stimulation of postsynaptic dopamine D₂-type receptors within the caudate-putamen in the brain.</p> <p>Restless Leg Syndrome: The precise mechanism of action of ropinirole hydrochloride as a treatment for Restless Legs Syndrome (also known as Ekbom Syndrome) is unknown but neuropharmacological evidence suggests primary dopaminergic system involvement.</p>
Contraindications	<p>Ropinirole HCL tablets are contraindicated for patients known to have hypersensitivity to the product.</p>
Pregnancy Comments	<p>Pregnancy Studies performed in pregnant rats during organogenesis (20 mg/kg on gestation days 6 and 7 followed by 20, 60, 90, 120, or 150 mg/kg on gestation days 8 through 15) resulted in decreased fetal body weight at 60 mg/kg/day, increased fetal death at 90 mg/kg/day, and digital malformations at 150 mg/kg/day (24, 36, and 60 times the maximum recommended clinical dose on a mg/m² basis, respectively).</p> <p>Nursing Mothers Studies in rats have shown that ropinirole hydrochloride and/or its metabolite(s) is excreted in breast milk. It is not known whether this drug is excreted in human milk.</p>
Pregnancy Category	<p>C</p>

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Section 4. First aid measures

General	Remove from exposure. Remove contaminated Clothing. Person developing serious hypersensitivity reaction must receive medical attention
Overdose Treatment	It is anticipated that the symptoms of overdose with ropinirole hydrochloride will be related to its dopaminergic activity. General supportive measures are recommended. Vital signs should be maintained, if necessary. Removal of any unabsorbed material (e.g., by gastric lavage) should be considered.

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. Storage / Spill / Disposal Measures

Storage	Store at 20°-25°C (68°-77°F) Protect from light and moisture. Close container tightly after each use.
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.

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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	Ropinirole Hydrochloride Tablets equivalent to 0.25 mg of ropinirole are white-colored, round-shaped, film-coated tablets debossed with "ZF22" on one side and plain on other side		
	Ropinirole Hydrochloride Tablets equivalent to 0.5 mg of ropinirole are yellow-colored, round-shaped, film-coated tablets, debossed with "ZF23" on one side and plain on the other side.		
	Ropinirole Hydrochloride Tablets equivalent to 1 mg of ropinirole are green-colored, round-shaped, film-coated tablets, debossed with "ZF24" on one side and plain on the other side.		
	Ropinirole Hydrochloride Tablets equivalent to 2 mg of ropinirole are pink-colored, round-shaped, film-coated tablets, debossed with "ZF25" on one side and plain on the other side.		
	Ropinirole Hydrochloride Tablets equivalent to 3 mg of ropinirole are purple-colored, round-shaped, film-coated tablets, debossed with "ZF42" on one side and plain on the other side.		
	Ropinirole Hydrochloride Tablets equivalent to 4 mg of ropinirole are brown-colored, round-shaped, film-coated tablets, debossed with "ZF43" on one side and plain on the other side.		
	Ropinirole Hydrochloride Tablets equivalent to 5 mg of ropinirole are blue-colored, round-shaped, film-coated tablets, debossed with "ZF26" on one side and plain on the 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

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Reactivity in water	No Data Available	Evaporation rate	No Data Available
Percentage Volatile by volume	No Data Available	Specific gravity	No Data Available
Vapour pressure	No Data Available		
Other information	Ropinirole hydrochloride is a white to cream-colored crystalline powder with a melting range of 241° to 245°C and a solubility of 133 mg/mL 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	No data available.

Section 11. Ecological information

No data available on Ecotoxicity

Section 12. Other information

None

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Supersedes Edition of: New Edition

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.