Safety Data Sheet
RISPERIDONE ORALLY DISINTEGRATING TABLETS

Strength: 0.5, 1, 2 mg. **Pack Size:** 30 Tablets per bottle **Revision No.:** 02

EMERGENCY OVERVIEW

Each RISPERIDONE ORALLY DISINTEGRATING TABLETS intended for oral administration contains Risperidone and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

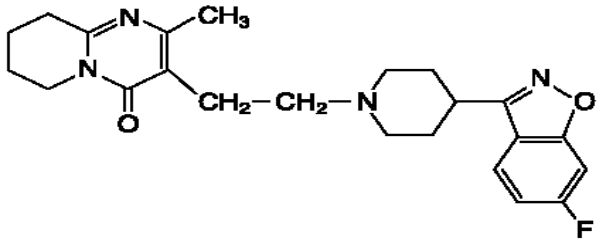
Section 1. Identification

Identification of the product

Product name: RISPERIDONE ORALLY DISINTEGRATING TABLETS

Chemical Formula: $C_{23}H_{27}FN_4O_2$

Chemical Name: 3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]-6,7,8,9-tetrahydro-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one



Manufacturer / supplier identification

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

Address: Sarkhej – Bavla. N.H. 8A, Moraiya. Tal. Sanand. Dist. Ahmedabad – 382210. State: Gujarat. India

Contact for information: Tel.: +91 79 6868100 Fax: +91 79 3750319

Emergency Telephone No. Tel.: +91 79 6868100

Recommended use / Therapeutic Category Psychotropic agent

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Restriction on Use / Contraindications Hypersensitivity reactions, including anaphylactic reactions and angioedema, have been observed in patients treated with risperidone. Therefore, risperidone tablets are contraindicated in patients with a known hypersensitivity to the product.

Section 2. Hazard(s) Information

Dose and Administration

Schizophrenia
In Adult, Usual Initial Dose
Risperidone tablets can be administered once or twice daily. Initial dosing is generally 2 mg/day. Dose increases should then occur at intervals not less than 24
hours, in increments of 1 - 2 mg/day, as tolerated, to a recommended dose of 4 to 8 mg/day.

Maintenance Therapy
While it is unknown how long a patient with schizophrenia should remain on risperidone tablets, the effectiveness of risperidone tablets 2 mg/day to 8 mg/day.

Bipolar Mania Adults:
Usual Dose Risperidone should be administered on a once-daily schedule, starting with 2 mg to 3 mg per day.

Adverse Effects

Body as a whole - general disorders
Back pain, Fatigue, Chest pain, Fever, Asthenia, Syncope and Edema.

Cardiovascular disorders, general
Hypotension postural, Hypotension

Central and peripheral nervous system disorders
Parkinsonism, Dizziness, Dystonia, Akathisia, Dyskinesia

Gastrointestinal system disorders
Dyspepsia , Nausea. Constipation, Abdominal pain, Mouth dry, Saliva increased, Diarrhea

Hearing and vestibular disorders
Earache

Heart rate and rhythm disorders
Tachycardia, Arrhythmia

Over Dose Effect

Premarketing experience included eight reports of acute risperidone tablets overdosage with estimated doses ranging from 20 to 300 mg and no fatalities. In general, reported signs and symptoms were those resulting from an exaggeration of the drug's known pharmacological effects, i.e., drowsiness and sedation, tachycardia and hypotension, and extrapyramidal symptoms.

Contraindications

Hypersensitivity reactions, including anaphylactic reactions and angioedema, have been observed in patients treated with risperidone. Therefore, risperidone tablets are contraindicated in patients with a known hypersensitivity to the product.

Medical Condition

Cerebrovascular Adverse Events, Including Stroke, in Elderly Patients With Dementia-Related Psychosis Cerebrovascular adverse events (e.g., stroke, transient ischemic attack), including fatalities

Neuroleptic Malignant Syndrome (NMS), A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with antipsychotic drugs.

Tardive Dyskinesia, A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsychotic drugs.

Hyperglycemia and Diabetes Mellitus, Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported.

Orthostatic Hypotension, Risperidone tablets may induce orthostatic hypotension associated with dizziness, tachycardia, and in some patients, syncope, especially during the initial dose-titration period, probably reflecting its alpha-adrenergic antagonistic properties.

Potential for Cognitive and Motor Impairment, Somnolence was a commonly reported adverse event associated with risperidone tablets treatment, especially when ascertained by direct questioning of patients.

Dysphagia, Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in patients with advanced Alzheimer's dementia.

Body Temperature Regulation, Disruption of body temperature regulation has been attributed to antipsychotic agents. Both hyperthermia and hypothermia have been reported in association with oral risperidone tablets use. Caution is advised when prescribing for patients who will be exposed to temperature extremes.

Antiemetic Effect, Risperidone has an antiemetic effect in animals; this effect may also occur in humans, and may mask signs and symptoms of overdosage with certain drugs or of conditions such as intestinal obstruction, Reye's syndrome, and brain tumor.

Suicide, The possibility of a suicide attempt is inherent in patients with schizophrenia and bipolar mania.

Pregnancy Comments

The teratogenic potential of risperidone was studied in three Segment II studies in Sprague-Dawley and Wistar rats (0.63-10 mg/kg or 0.4 to 6 times the maximum recommended human dose [MRHD] on a mg/m2 basis) and in one Segment II study in New Zealand rabbits (0.31-5 mg/kg or 0.4 to 6 times the MRHD on a mg/m2 basis). The incidence of malformations was not increased compared to control in offspring of rats or rabbits given 0.4 to 6 times the MRHD on a mg/m2 basis. In three reproductive studies in rats (two Segment III and a multigenerational study), there was an increase in pup deaths during the first 4 days of lactation at doses of 0.16-5 mg/kg or 0.1 to 3 times the

MRHD on a mg/m2 basis. It is not known whether these deaths were due to a direct effect on the fetuses or pups or to effects on the dams.

Pregnancy Category **C**

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component :		
Risperidone	Not Found	747-36-4
Inactive Ingredients :		
Aspartame	Not Found	22839-47-0
Butylated methacrylate copolymer	Not Found	97-88-01
Calcium stearate	Not Found	1592-23-0
Crospovidone	Not Found	9003-39-8
Flavor firmenich powder peppermint	Not Found	761-75-51
Propylene glycol	Not Found	57-55-6
Sodium lauryl sulfate	Not Found	151-21-3
Mannitol	Not Found	3969-84-4

Section 4. First - aid measures

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

Overdose Treatment In case of acute overdosage, establish and maintain an airway and ensure adequate oxygenation and ventilation. Gastric lavage and administration of activated charcoal together with a laxative should be considered. The possibility of obtundation, seizures, or dystonic reaction of the head and neck following overdose may create a risk of aspiration with induced emesis. There is no specific antidote to risperidone tablets. Therefore, appropriate supportive measures should be instituted. Hypotension and circulatory collapse should be treated with appropriate measures, such as intravenous fluids and/or sympathomimetic agents (epinephrine and

dopamine should not be used, since beta stimulation may worsen hypotension in the setting of risperidone-induced alpha blockade).Close medical supervision and monitoring should continue until the patient recovers.

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 25°C (77°F); Protect from light and moisture.
Dispense in a tight, light-resistant container. Keep out of reach of children.

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	Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Section 9. Physical and chemical properties

Appearance

Risperidone Orally Disintegrating Tablets, 0.5 mg are white to off-white, round, tablets debossed with “ZD 22” on one side and plain on the other side.

Risperidone Orally Disintegrating Tablets, 1 mg are white to off-white, round, tablets debossed with “ZD 21” on one side and plain on other side.

Risperidone Orally Disintegrating Tablets, 2 mg are white to off-white, round, tablets debossed with “ZD 20” 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
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 Risperidone, USP is a white to slightly beige powder. It is practically insoluble in water, freely soluble in methylene chloride, and soluble in methanol and 0.1 N HCl.

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 Tablets.

Other No data available

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 078516

Section 16. Other information

None

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