ajanta pharma limited

SAFETY DATA SHEET

RISPERIDONE TABLETS, USP 0.25 MG, 0.5 MG, 1 MG, 2 MG, 3 MG, and 4 MG

EMERGENCY OVERVIEW

RISPERIDONE TABLETS contain Risperidone and excipients generally considered to be non-toxic and non-hazardous in small quantities under conditions of normal occupational exposure and within the IIG limits prescribed by USFDA for oral Tablets.

Section 1. Identification of the substance

Identification of the product

Product name	**:**	RISPERIDONE TABLETS, USP
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.
Therapeutic Category	**:**	Psychotropic agent
Marketed by	**:**	Ajanta Pharma USA Inc. Bridgewater, NJ 08807. Made in India
Contact Information	**:**	1-888-664-7744

Section 2. Composition / information on ingredients

Active ingredient	**Exposure Limit**	**CAS No.**
Risperidone	Not Found	747-36-4

Inactive ingredients: colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, propylene glycol (except 1mg), sodium lauryl sulphate, sodium starch glycolate and polyethylene glycol (1mg). Tablets of 0.25 mg, 0.5 mg, 2 mg, 3 mg, and 4 mg also contain talc and titanium dioxide. 0.25 mg, 0.5 mg, and 3 mg tablets contain FD&C Yellow # 6 aluminum lake, the 2 mg tablets contain yellow iron oxide; the 4 mg tablets contain iron oxide red.

Section 3. Health Hazards Information

Dose and Administration **:** **For Treatment of Schizophrenia**
In Adult, Usual Initial Dose
Risperidone tablets, USP 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, USP the effectiveness of risperidone tablets, USP 2 mg/day to 8 mg/day.

For Treatment of Bipolar Mania

Adults: Usual Dose

Risperidone, USP should be administered on a once-daily schedule, starting with 2 mg to3 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, USP overdose with estimated ingestion ranging from 20 to 300 mg with 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, USP. Therefore, risperidone tablets, USP are contraindicated in patients with a known hypersensitivity to the product.

Medical Conditions : 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, USP 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, USP 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, USP use. Caution is advised when prescribing for patients who will be exposed to temperature extremes.
Antiemetic Effect, Risperidone, USP 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 Precautions **:** The teratogenic potential of risperidone, USP 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/m^2 basis) and in one Segment IIstudy in New Zealand rabbits (0.31-5 mg/kg or 0.4 to 6 times the MRHD on a mg/m^2 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/m^2 basis. In three reproductive studies in rats (two Segment III and amultigenerational 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/m^2 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 4. First aid measures

General : Isolate the individual from exposure. Remove contaminated Clothing. In case of serious hypersensitivity reaction seek immediate medical attention.

Overdose Treatment : In case of acute over dosage, 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, USP. 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 Hazards and Handling

Flash Point : Not Reported
Auto-Ignition Temperature : Not Reported
Extinguishing Media : Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.
Upper Flammable Limit : Not a flammable material.
Lower Flammable Limit : Not a flammable material
Fire and Explosion Hazard : This material is assumed to be combustible. Keep it away from the open fires.
Fire Fighting Procedures : As with all fires, evacuate personnel to a safe area. Fire fighter should use self contained breathing equipment and

protective clothing.

Hazardous Combustion by Products	:	Carbon dioxide, carbon monoxide, oxides of nitrogen, oxides of sulfur, oxides of sodium, hydrogen chloride

Section 6. Storage / Spill / Disposal Measures

Storage	:	Risperidone Tablets, USP should be stored 20° to 25°C (68° to 77°F); excursions permitted between 15°to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Protect from light and moisture. Keep out of reach of children.
Spill Response	:	In case of tablet spill wear chemically compatible gloves and pickup spilled product manually or using high efficiency vacuum cleaner.
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 direct 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	:	**Risperidone Tablets, USP** 0.25 mg are orange, circular, biconvex, film coated tablets, engraved with ‘RI1’ on one side and plain on other **Risperidone Tablets, USP** 0.5 mg are orange, circular, biconvex, film coated tablets, engraved with ‘RI2’ on one side and plain on other **Risperidone Tablets, USP** 1 mg are white to off white, circular, biconvex, film coated tablets, engraved with

		'RI3' on one side and plain on other **Risperidone Tablets, USP** 2 mg are yellow, circular, biconvex film coated tablets, engraved with 'RI4' on one side and plain on other **Risperidone Tablets, USP** 3 mg are orange, capsule shaped, biconvex film coated tablets, engraved with 'RI5' on one side and plain on other **Risperidone Tablets, USP** 4 mg are brown, ovaloid, biconvex, film coated tablets, engraved with 'RI6' on one side and plain on other
Solubility in water	:	No Data Available
Odor	:	Odorless
Boiling point	:	No Data Available
Melting Point	:	No Data Available
Evaporation rate	:	No Data Available
Specific gravity	:	No Data Available
Vapor density	:	No Data Available
Reactivity in water	:	No Data Available
Evaporation rate	:	No Data Available
Percentage Volatile by volume	:	No Data Available
Vapor 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 9. Physical Hazards to Product

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. In finished dosage form there is least possibility that product will undergo any hazardous reaction.
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 orally administered tablet formulation.

Section 11. Ecological information

No data available on Ecotoxicity of API. In the finished product form there is no potential for air borne contamination since the product is in compressed coated tablet form.

Section 12. Disposal Consideration

Waste Disposal Considerations: Dispose of material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended. At home: Discard away from children's reach.

Section 13. Transport information

This product is authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals.

DOT: Not Regulated
IATA: Not Regulated
IMDG: Not Regulated

Section 14. Regulatory information

DEA: Risperidone, USP is not a controlled substance.

FDA: Risperidone Tablets, USP is an approved prescription medication.

Inventory Status: This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.
This material is not listed on the DSL Inventory but is exempt.

Section 15. Other Data

Not Applicable.

Date: 18-Nov-2021

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION