LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material	**Risperidone for ER Injectable Suspension**
Identified uses of the substance or mixture	Pharmaceutical
Manufacturer	**Nanomi B.V.,** a Lupin Group Company, 7575 EJ, Oldenzaal, The Netherlands.
Distributed by	**Lupin Pharmaceuticals, Inc**. Naples, FL 34108 United States.

Section 2: Hazard(s) Identification

Health	Do not use it until all safety precautions have been read and understood. Known hypersensitivity to risperidone or any excipients in risperidone for extended-release injectable suspension. Please refer to the product information/ Package insert for appropriate consumer-specific information about this product when used according to the physician's directions.
Environment	Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 3: Composition/Information on Ingredients

Risperidone extended-release injectable suspension 25 mg, 37.5 mg, 50 mg.

Ingredients	CAS No.	Ingredients	CAS No.
Risperidone	106266-06-2	Polysorbate 20	9005-64-5
75/25 DL-lactide/glycolide copolymer	26780-50-7	Citric acid anhydrous	77-92-9
Sodium carboxymethyl cellulose	9004-32-4	Sodium Hydroxide NF	1310-73-2
Disodium Hydrogen Phosphate Dihydrate	10028-24-7	Water for Injection	-
Sodium chloride	7647-14-5	-	-

* The exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: First-Aid Measures

Inhalation	Move the victim into fresh air. Apply artificial respiration if the victim is not breathing. If breathing is difficult, give oxygen. Get medical attention.
Skin contact	Take off contaminated clothing. Wash the exposed parts of the body with plenty of soap and water. Get medical attention if irritation persists.
Eye contact	Rinse immediately with plenty of water for at least 15 minutes keeping eyelids open. Get medical attention, if irritation persists.
If swallowed	Never give fluids if the patient is unconscious. If the person is conscious, rinse the mouth with water. In case of spontaneous vomiting be sure that vomitus can freely drain due to the danger of suffocation. Do not induce vomiting. Get medical attention.

Section 5: Fire-Fighting Measures

Specific hazards during firefighting	None known.
Extinguishing Media	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide. Do not use a water jet.
Special Firefighting Procedures	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Hazardous Combustion Products	Carbon oxides, Nitrogen oxides, Hydrogen fluoride.

Section 6: Accidental Release Measures

Personal Precautions	Ventilate confined areas. Avoid contact with skin and eyes. Use rubber gloves and safety goggles. Emergency responders use suitable personal protective equipment.
Environmental Precautions	Prevent spillage on the floor/ground. Inform respective authorities in case of seepage into the water course or sewage system.
Clean-up Methods	Absorb spills with inert absorbent material and transfer them into a labeled container for disposal. Wash spill site and ventilate area.

Section 7: Handling and Storage

Handling	Keep away from heat/sparks/open flames/hot surfaces. Protect from light. Keep out of the reach of children.
Storage	The entire dose pack should be stored in the refrigerator (36°-46°F; 2°-8°C) and protected from light. If refrigeration is unavailable, risperidone for extended-release injectable suspension can be stored at temperatures not exceeding 77°F (25°C) for no more than 7 days prior to administration. Do not expose unrefrigerated products to temperatures above 77°F (25°C).

Section 8: Exposure Controls/Personal Protection

Engineering Measures/Controls:	Ensure adequate ventilation, especially in enclosed spaces.
Personal Protective Equipment:	Respiratory: Respiratory protection is generally not needed during routine conditions of use of this product. Eye/Face: Avoid contact with the eye. No special controls or personal protection are required under conditions of intended use. Skin/Body: No special personal protection is required under conditions of intended use.

Section 9: Physical and Chemical Properties

HOW SUPPLIED	Risperidone for extended-release injectable suspension is available in dosage strengths of 25 mg, 37.5 mg or 50 mg risperidone. It is provided as a single-dose pack, consisting of a vial containing the risperidone microspheres, a pre-filled syringe containing 2 mL of diluent for risperidone for extended-release injectable suspension, a vial adapter, and two Terumo SurGuard® 3 Needles for intramuscular injection (a 21 G UTW 1-inch needle with needle protection device for deltoid administration and a 20 G TW 2-inch needle with needle protection device for gluteal administration). 25-mg vial/kit (NDC 70748-445-13): 78 mg (equivalent to 25 mg of risperidone) of an off-white to slightly yellow powder provided in a vial with a pink flip-off cap. 37.5-mg vial/kit (NDC 70748-446-13): 116 mg (equivalent to 37.5 mg of risperidone) of an off-white to slightly yellow powder provided in a vial with a green flip-off cap. 50-mg vial/kit (NDC 70748-447-13): 152 mg (equivalent to 50 mg of risperidone) of an off-white to slightly yellow powder provided in a vial with a blue flip-off cap.

Section 10: Stability and Reactivity

Stability	Stable under recommended storage conditions.
Reactivity	None known.
Hazardous reactions	None known.
Conditions to avoid	Keep away from heat/sparks/open flames/hot surfaces. Protect from light.
Hazardous decomposition products	Carbon oxides, Nitrogen oxides, Hydrogen fluoride.

Section 11: Toxicological Information

Inhalation	Acute inhalation toxicity: None known.
Skin Contact	Acute Immediate - None known. Chronic (Delayed) - None known.

Ingestion	Acute Immediate - Not expected to be an exposure route. Chronic (Delayed) - None known.
Eye Contact	Acute Immediate - None known Chronic (Delayed) - None known
Carcinogenicity	Carcinogenesis – Oral Risperidone was administered in the diet at doses of 0.63, 2.5, and 10 mg/kg for 18 months to mice and for 25 months to rats. These doses are equivalent to approximately 0.2, 0.75, and 3 times (mice) and 0.4, 1.5, and 6 times (rats) the MRHD of 16 mg/day, based on mg/m2 body surface area. A maximum tolerated dose was not achieved in male mice. Carcinogenesis – Intramuscular Risperidone was evaluated in a 24-month carcinogenicity study in which SPF Wistar rats were treated every 2 weeks with intramuscular (IM) injections of either 5 mg/kg or 40 mg/kg of risperidone. These doses are 1 and 8 times the MRHD (50 mg) on a mg/m2 basis. A control group received injections of 0.9% NaCl, and a vehicle control group was injected with placebo microspheres. There was a significant increase in pituitary gland adenomas, endocrine pancreas adenomas, and adrenomedullary pheochromocytomas at 8 times the IM (intramuscular) MRHD on a mg/m2 basis. The incidence of mammary gland adenocarcinomas was significantly increased in female rats at both doses (1 and 8 times the IM (intramuscular) MRHD on a mg/m2 basis). A significant increase in renal tubular tumors (adenoma, adenocarcinomas) was observed in male rats at 8 times the IM (intramuscular) MRHD on a mg/m2 basis. Plasma exposures (AUC) in rats 39 were 0.3 and 2 times (at 5 and 40 mg/kg, respectively) the expected plasma exposure (AUC) at the IM (intramuscular) MRHD. Mutagenesis No evidence of mutagenic or clastogenic potential for risperidone was found in the *in vitro* tests of Ames gene mutation, the mouse lymphoma assay, rat hepatocyte DNA-repair assay, the chromosomal aberration test in human lymphocytes, Chinese hamster ovary cells, or in the *in vivo* micronucleus test in mice, and the sex-linked recessive lethal test in *Drosophila*. In addition, no evidence of mutagenic potential was found in the *in vitro* Ames reverse mutation test for risperidone for extended-release injectable suspension. Impairment of Fertility Oral risperidone (0.16 to 5 mg/kg) impaired mating, but not fertility, in reproductive studies at doses 0.1 to 3 times the oral maximum recommended human dose (MRHD of 16 mg/day) based on mg/m2 body surface area. The effect appeared to be in females, since impaired mating behavior was not noted in the male fertility study. In a subchronic study in Beagle dogs in which oral risperidone was administered at doses of 0.31 to 5 mg/kg, sperm motility and concentration were decreased at doses 0.6 to 10 times the oral MRHD on a mg/m2 basis. Dose-related decreases were also noted in serum testosterone at the same doses. Serum testosterone and sperm values partially recovered but decreased after treatment was discontinued. A no-effect dose could not be determined in either rat or dog.

Section 12: Ecological Information

Eco toxicity	Ecology-general May cause long-term adverse effect to aquatic environment. Acute aquatic toxicity Data not available.
Persistence and biodegradability	The substance is not rapidly biodegradable.

Section 13: Disposal Considerations

Dispose of material according to federal, state, and local disposal regulations.

Section 14: Transport Information

IATA/ICAO - Not Regulated

IATA Proper Shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard Class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A

IMDG - Not Regulated

IMDG Proper Shipping Name	:	N/A
IMDG UN/ID No	:	N/A
IMDG Hazard Class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

DOT - Not Regulated

DOT Proper Shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

Section 16: Other Information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Lupin shall not be held liable for any damage resulting from handling or from contact with the above product. Lupin reserves the right to revise this SDS.