

MATERIAL SAFETY DATA SHEET

Date: 01/08/2015

Generic Name: Pramipexole Dihydrochloride Tablets, 0.25 mg

Brand Equivalent: MIRAPEX[®] (a registered trademark of Boehringer Ingelheim)

SECTION 1: MATERIAL IDENTIFICATION

Common Name	Pramipexole Dihydrochloride Tablets
Synonyms	Pramipexole Dihydrochloride Monohydrate
Formula	C ₁₀ H ₁₉ Cl ₂ N ₃ S.H ₂ O
CAS Number	[191217-81-9]
Therapeutic Category	Antiparkinson
Chemical Name	6(S)-6-N-Propyl-4,5,6,7-tetrahydro-1,3-benzothiazole-2,6-diamine dihydrochloride monohydrate. (or) (S)-2-amino-4,5,6,7-tetrahydro-6-(propylamino)benzothiazole dihydrochloride monohydrate.
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 20 Davids Drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723

SECTION 2: HAZARDOUS INGREDIENTS

None

SECTION 3: PHYSICAL DATA

Melting Point

N/A

Boiling Point

N/A

Water Solubility

Greater than 20% (20 C)

Appearance

White to off white, oval, flat, beveled edge uncoated tablets debossed on one side with 'S' on the left side of bisect and 'G' on the right side of bisect and other side '1' on the left side and '27' on the right side of the bisect.

Odor

None

SECTION 4: FIRE AND EXPLOSION DATA

Flash Point

N/A

Flammable Limits Volume

N/A

Auto Ignition Temperature

435° Active Ingredient

Extinguish Media

Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Special firefighting procedures

Evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use water spray to keep fire-exposed containers cool and protect against all exposures.

Unusual fire and explosion hazards

This material presents a dust explosion hazard. It can burn in a fire, producing flammable fumes including acid gases and oxides of carbon, nitrogen and sulfur.
Minimum Ignition Energy 42 mJ at 22.5°C

SECTION 5:

REACTIVITY

Stability

Stable under normal conditions

Conditions to Avoid

Take precautionary measures against static discharge. Keep away from heat and sources of ignition. Is slightly sensitive to friction.

Incompatible Materials

Strong oxidizers

Hazardous Decomposition Products

When heated to decomposition or under fire conditions, material emits toxic fumes including acid gases and oxides of nitrogen, carbon and sulfur.

Hazardous Polymerization

Will not occur.

SECTION 6: HEALTH HAZARDS

ACUTE TOXICITY for ACTIVE INGREDIENT:

LOWEST PUBLISHED TOXIC DOSE/CONC

Child

TDLo - ROUTE: Oral; DOSE: 91 µg/kg

TOXIC EFFECTS: *Behavioral* - Somnolence (general depressed activity) *Gastrointestinal* - Nausea or vomiting

LOWEST PUBLISHED LETHAL DOSE/CONC

Mouse

LDLo - ROUTE: Oral; DOSE: 1700 mg/kg

TOXIC EFFECTS: *Behavioral* – Tremor, Convulsions or effect on seizure threshold, Ataxia

LD50/LC50

Rat

LD50 - ROUTE: Oral; DOSE: 809 mg/kg (Male)

TOXIC EFFECTS: *Behavioral* – Tremor, Convulsions or effect on seizure threshold, Ataxia

LD 50- Route: Oral: LD50: 548 mg/kg (Female)

Sensitization: Maximization Test (GPMT) mild sensitizing potential (guinea pig)

Ames Test: Negative

Reproductive Toxicity for Active ingredient

Doses of Pramipexole of 2.5 mg/kg/day (5.4 times the highest human dose on a surface area basis) prolonged estrous cycles and inhibited implantation. This is a common effect of dopamine agonists in rats and does not necessarily translate to humans. Treatment of pregnant rats after implantation with Pramipexole 1.5 mg/kg/d resulted in an increase in embryo resorptions. Serum concentrations of Pramipexole at this dose were more than four times the concentrations achieved in humans on therapy.

In pregnant rabbits, administration of 10 mg/kg/d did not produce adverse pregnancy effects. Serum concentrations were 71 times those achieved in humans on therapy. The rabbit, like the human, does not rely on prolactin for successful pregnancy.

In the rat nidation study, an increase in early resorptions occurred in most dams. However the surviving fetuses, as well as the progeny of the intermediate and low dose groups, were normal. The high dose of the active ingredient led to severe maternotoxicity.

SECTION 7: FIRST AID

Inhalation	Remove from area to fresh air. Seek medical attention if respiratory irritation develops or if breathing becomes difficult.
Ingestion	Give 3-4 glasses of water, but DO NOT induce vomiting. If vomiting occurs, give fluids again. Get medical attention to determine whether vomiting or evacuation of stomach is necessary. Do not give anything by mouth to an unconscious or convulsing person.
Skin Contact	Remove contaminated clothing. Wash affected areas with plenty of water, and soap if available, for several minutes. Seek medical attention if irritation or rash develops and persists.
Injection	In case of accidental injection, wash and thoroughly disinfect, get medical attention.
Eye Contact	Flush eyes with large amounts of running water for 15 minutes. Get immediate medical attention.

SECTION 8: ACCIDENTAL RELEASE MEASURES

Spills/Leaks	Wear approved respirator and chemically compatible gloves if containers have been compromised. Vacuum or sweep up spillage. Avoid creating dust. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before reuse. Ventilate area; wash down spill site and control wash water.
Waste Disposal	Dispose of in accordance with local, state and federal regulations. Recommended method is incineration.

SECTION 9: SPECIAL HANDLING

Handling	Avoid contact with eyes, skin or clothing. Avoid breathing dust. Avoid generating dust. Store in tight, light-resistant containers at a temperature less than 30°C.
Other Precautions	Wash thoroughly after handling material. Wear fresh clothing daily. Wash contaminated clothing before reuse.

SECTION 10: MSDS PREPARATION INFORMATION

New: 01/08/2015

SECTION 11: DISCLAIMER

The above information is believed to be correct but should only be used as a guide. ScieGen Pharmaceuticals, Inc. disclaims any express or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental or consequential damages resulting from reliance on the above information.