

## MATERIAL SAFETY DATA SHEET

### SECTION-1: DETAILS ABOUT THE CHEMICAL PRODUCT AND COMPANY

#### IDENTIFICATION

##### Drug Product name:

Lurasidone Hydrochloride Tablets 20 mg, 40 mg, 60 mg, 80 mg, 120 mg

##### Distributed by:

M/s Slate Run Pharmaceuticals, LLC, 277 W,  
Nationwide Blvd, Suite 260, Columbus, Ohio 43215

##### Manufactured by:

Piramal Pharma Limited,  
Plot 67-70, Sector II Pithampur Dist., Dhar, Madhya Pradesh-454775, India

### SECTION-2: HAZARD(S) IDENTIFICATION

Not considered hazardous when handled under normal conditions with good housekeeping.

### SECTION-3: COMPOSITION/INFORMATION ON INGREDIENTS

Drug Name	Weight in %
Lurasidone Hydrochloride Tablets	100%

List of the excipients used in manufacturer of tablets are given below.

Lurasidone Hydrochloride Micronized
Mannitol
Maize Starch
Microcrystalline Cellulose
Hypromellose
Croscarmellose Sodium
Colloidal Silicon Dioxide
Magnesium Stearate
Opadry White 03F580061
Opadry Green 03F510070

#### Piramal Pharma Limited

Plot 67-70, Sector II Pithampur, Dist: Dhar, Madhya Pradesh - 454775 (India)  
Corporate Office: Ground Floor, Piramal Ananta, Agastya Corporate Park, LBS Marg, Kamani Junction, Kurla West, Mumbai - 400070.

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### SECTION-4: FIRST AID MEASURES

**General Advice** - Consult a physician if necessary. Remove to fresh air.

**Inhalation** - Remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration.

**Eye contact** - Wash with plenty of water.

**Skin contact** - Wash skin with soap and water.

**Ingestion** - Never give anything by mouth to an unconscious person. Clean mouth with water.

### SECTION-5: FIRE-FIGHTING MEASURES

Not considered hazardous when handled under normal conditions with good housekeeping. In case of fire, use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

Ensure adequate ventilation, especially in confined areas. Prevent further leakage or spillage if safe to do so. Pick up and transfer to properly labelled containers.

### SECTION 7: HANDLING AND STORAGE

- a) Store under the following conditions: Dry place.
- b) Wear suitable protective clothing and gloves.

### SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

**Eye / face protection** - Wear safety glasses with side shields (or goggles).

**Skin and body protection** - Wear protective gloves and protective clothing.

**Respiratory protection** - No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

**General hygiene considerations** - Handle in accordance with good industrial hygiene and safety practice.

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### SECTION-9: PHYSICAL AND CHEMICAL PROPERTIES:

Physical state: Solid

Appearance: White / Green coloured film coated tablets

Melting point: No data

Boiling data: No data

Flask point: No data

Solubility: No data

### SECTION 10: STABILITY AND REACTIVITY

Not considered reactive material. Wear suitable protective clothing and gloves while handling. Material is stable at ambient temperature.

### SECTION-11: TOXICOLOGICAL INFORMATION

Not applicable

### SECTION-12: ECOLOGICAL INFORMATION

Persistence and degradability: No information available

Bio accumulative potential: No information available

Mobility in soil: No information available

### SECTION-13: DISPOSAL CONSIDERATIONS

Dispose of Material and Packaging in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

### SECTION 14: TRANSPORT INFORMATION.

Material Transport condition: Ambient temperature.

Environmental hazardous – Non-hazardous

Special precaution for user – No data available

Transport hazard – None (Material can be shipped through air)

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### SECTION 15: REGULATORY INFORMATION

USFDA approved ANDA# 212091

### SECTION 16: OTHER INFORMATION

Not applicable

**DISCLAIMER:** The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**END OF SAFETY DATA SHEET**