# LUPIN LIMITED
## SAFETY DATA SHEET

### Section 1: Identification

<table>
<thead>
<tr>
<th>Material</th>
<th>Moxifloxacin Ophthalmic Solution USP, 0.5%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Lupin Limited</td>
</tr>
<tr>
<td></td>
<td>Pithampur (M. P.), 454 775</td>
</tr>
<tr>
<td></td>
<td>India.</td>
</tr>
<tr>
<td>Distributor</td>
<td>Lupin Pharmaceuticals, Inc.</td>
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<tr>
<td></td>
<td>111 South Calvert Street,</td>
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<tr>
<td></td>
<td>Harborplace Tower, 21st Floor,</td>
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<tr>
<td></td>
<td>Baltimore, Maryland 21202</td>
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<tr>
<td></td>
<td>United States</td>
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<tr>
<td></td>
<td>Tel. 001-410-576-2000</td>
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<tr>
<td></td>
<td>Fax. 001-410-576-2221</td>
</tr>
</tbody>
</table>

### Section 2: Hazard(s) Identification

**Note**
This product is Non-Hazardous and is approved by the FDA. It is an aqueous solution and is not considered to constitute a Hazard.

**Health**
Moxifloxacin ophthalmic solution is contraindicated in patients with a history of hypersensitivity to moxifloxacin, to other quinolones, or to any of the components in this medication.

**Environment**
No information is available about the potential of this product to produce adverse environmental effects.

### Section 3: Composition/Information on Ingredients

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moxifloxacin Hydrochloride USP</td>
<td>186826-86-8</td>
</tr>
</tbody>
</table>

### Section 4: First-Aid Measures

**Ingestion**
Flush the mouth with water. Obtain medical attention.

**Inhalation**
Move individual to fresh air. Obtain medical attention.
Skin Contact
Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Eye Contact
Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment
Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient’s airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient’s vital signs, blood gases, serum electrolytes, etc.

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures

Fire and Explosion Hazards
Assume that this product is capable of sustaining combustion.

Extinguishing Media
Water spray, carbon dioxide, dry chemical powder or appropriate foam.

Special Firefighting Procedures
For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.

Hazardous Combustion Products
Hazardous combustion or decomposition products are expected when the product is exposed to fire.

Section 6: Accidental Release Measures

Section 6, Accidental release measures

Personal Precautions
Wear protective clothing and equipment consistent with the degree of hazard.

Environmental Precautions
For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

Clean-up Methods
Collect and place it in a suitable, properly labeled container for recovery or disposal.

Section 7: Handling and Storage

Section 7, Handling and storage

Handling
No special measures required.
**Section 8: Exposure Controls/ Personal Protection**

Section 8, Exposure controls/personal protection

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

**Section 9: Physical and Chemical Properties**

Section 9, Physical and chemical properties

**Physical Form**

**HOW SUPPLIED**

Moxifloxacin ophthalmic solution USP, 0.5% is supplied as a sterile ophthalmic solution in a sterile 5 mL natural low density polyethylene bottle fitted with a natural low density polyethylene nozzle and sealed with tan colored high density polyethylene cap as follows:

3 mL in 5 mL bottle (NDC 68180-422-01)

**Section 10: Stability and Reactivity**

Section 10, Stability and reactivity

Stable under recommended storage conditions.

**Section 11: Toxicological Information**

Section 11, Toxicological information

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

Long-term studies in animals to determine the carcinogenic potential of moxifloxacin have not been performed. However, in an accelerated study with initiators and promoters, moxifloxacin was not carcinogenic in rats following up to 38 weeks of oral dosing at 500 mg/kg/day (approximately 21,700 times the highest recommended total daily human ophthalmic dose for a 50 kg person, on a mg/kg basis).

Moxifloxacin was not mutagenic in four bacterial strains used in the Ames *Salmonella* reversion assay. As with other quinolones, the positive response observed with moxifloxacin in strain TA 102 using the same assay may be due to the inhibition of DNA gyrase. Moxifloxacin was not mutagenic in the CHO/HGPRT mammalian cell gene mutation assay. An equivocal result was obtained in the same assay when v79 cells were used. Moxifloxacin was clastogenic in the v79 chromosome aberration assay, but it did not induce unscheduled DNA synthesis in cultured rat hepatocytes. There was no evidence of genotoxicity *in vivo* in a micronucleus test or a dominant lethal test in mice.
Moxifloxacin had no effect on fertility in male and female rats at oral doses as high as 500 mg/kg/day, approximately 21,700 times the highest recommended total daily human ophthalmic dose. At 500 mg/kg orally there were slight effects on sperm morphology (head-tail separation) in male rats and on the estrous cycle in female rats.

### Section 12: Ecological Information

**Section 12: Ecological Information**

No relevant studies identified.

### Section 13: Disposal Considerations

**Section 13: Disposal Considerations**

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

### Section 14: Transport Information

**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

**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.