1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

Material: Metformin Hydrochloride Extended-Release Tablets
500 mg and 1000 mg

Manufacturer: Lupin Limited
Goa 403 722
INDIA.

Distributor: Lupin Pharmaceuticals, Inc.
Harborplace Tower, 21st Floor
111, South Calvert Street
Baltimore, MD 21202
United States
Tel. 001-410-576-2000
Fax 001-410-576-2221

2. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS</th>
<th>Quantity</th>
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<tbody>
<tr>
<td>Metformin Hydrochloride</td>
<td>1115-70-4</td>
<td>500 mg &amp; 1000 mg Tablets</td>
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<tr>
<td>Non-hazardous ingredients</td>
<td>---------</td>
<td>q.s.</td>
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3. HAZARDOUS IDENTIFICATION

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

Health
Metformin is contraindicated in patients with renal disease or renal dysfunction (e.g., as suggested by serum creatinine levels ≥1.5 mg/dL [males], ≥1.4 mg/dL [females] or abnormal creatinine clearance) which may also result from conditions such as cardiovascular collapse (shock), acute myocardial infarction, and septicemia.

Known hypersensitivity to metformin.

Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin. Metformin should be temporarily discontinued in patients undergoing radiologic studies involving intravascular administration of iodinated contrast materials, because use of such products may result in acute alteration of renal function.
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.

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

7. HANDLING AND STORAGE

Handling
No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.

Storage
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature]. Keep tightly closed (protect from moisture). Protect from light. Avoid excessive heat and humidity.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

9. PHYSICAL & CHEMICAL PROPERTIES

Physical Form
Metformin hydrochloride extended-release tablets are supplied as biconvex-shaped, film-coated extended-release tablets containing 500 mg or 1000 mg of metformin hydrochloride.

Metformin hydrochloride extended-release tablets 500 mg are extended-release, white to off-white, oval shaped, biconvex coated tablets debossed with “Q21” on one side and “LU” on the other side.

NDC 68180-336-07 bottles of 60
NDC 68180-336-01 bottles of 100
NDC 68180-336-02 bottles of 500

Metformin hydrochloride extended-release tablets 1000 mg are extended-release, white to off-white, oval shaped, biconvex coated tablets debossed with “Q22” on one side and “LU” on the other side.

NDC 68180-337-07 bottles of 60
NDC 68180-337-01 bottles of 100
NDC 68180-337-02 bottles of 500
10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

11. TOXICOLOGICAL INFORMATION

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Long-term carcinogenicity studies with metformin have been performed in rats (dosing duration of 104 weeks) and mice (dosing duration of 91 weeks) at doses up to and including 900 mg/kg/day and 1500 mg/kg/day, respectively. These doses are both approximately four times the maximum recommended human daily dose of 2000 mg based on body surface area comparisons. No evidence of carcinogenicity with metformin was found in either male or female mice. Similarly, there was no tumorigenic potential observed with metformin in male rats. There was, however, an increased incidence of benign stromal uterine polyps in female rats treated with 900 mg/kg/day.

There was no evidence of mutagenic potential of metformin in the following in vitro tests: Ames test (S. typhimurium), gene mutation test (mouse lymphoma cells), or chromosomal aberrations test (human lymphocytes). Results in the in vivo mouse micronucleus test were also negative. Fertility of male or female rats was unaffected by metformin when administered at doses as high as 600 mg/kg/day, which is approximately three times the maximum recommended human daily dose based on body surface area comparisons.

12. ECOLOGICAL INFORMATION

No relevant studies identified.

13. DISPOSAL CONSIDERATION

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

14. TRANSPORT INFORMATION

IATA/ICAO - Not Regulated

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MSDS : 050/01
Effective Date : 25/07/2011
15. REGULATORY INFORMATION

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

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 MSDS.