LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material: Fenofibrate Tablet USP 54 mg and 160 mg
Manufacturer: Lupin Limited
Goa - 403722
India
Distributor: Lupin Pharmaceuticals, Inc.
111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States
Tel. 001-410-576-2000
Fax. 001-410-576-2221

Section 2: Hazard(s) Identification

Fire and Explosion:
Expected to be non-combustible.

Health:
Fenofibrate is contraindicated in:
  • patients with severe renal impairment, including those receiving dialysis.
  • patients with active liver disease, including those with primary biliary cirrhosis and unexplained persistent liver function abnormalities.
  • patients with preexisting gallbladder disease.
  • nursing mothers.
  • patients with known hypersensitivity to fenofibrate or fenofibric acid.

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

Section 3: Composition/Information on Ingredients

Ingredients:
Fenofibrate USP 49562-28-9
Section 4: First-Aid Measures

Ingestion
If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention.

Inhalation
Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.

Skin Contact
Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.

Eye Contact
Flush eyes with plenty of water. Get medical attention.

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.

OVERDOSAGE
There is no specific treatment for overdose with fenofibrate. General supportive care of the patient is indicated, including monitoring of vital signs and observation of clinical status, should an overdose occur. If indicated, elimination of unabsorbed drug should be achieved by emesis or gastric lavage; usual precautions should be observed to maintain the airway. Because fenofibric acid is highly bound to plasma proteins, hemodialysis should not be considered.

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

#### 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

#### 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].
Protect from moisture. Keep out of reach of children.

### 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

#### Physical Form
Fenofibrate tablets USP are available in two strengths:

Fenofibrate tablets USP, 54 mg are yellow, round, biconvex, film coated tablets debossed with "LU" on one side and "J41" on the other side. They are available as follows:

- Bottles of 90  NDC 68180-362-09  
- Bottles of 500  NDC 68180-362-02  
- Bottles of 1000 NDC 68180-362-03  
- Carton of 100 (10 x 10) Unit-dose Tablets NDC 68180-362-13

Fenofibrate tablets USP, 160 mg are white to off-white oval shaped, biconvex film coated tablets, debossed with "LU" on one side and "J42" on the other side. They are available as follows:
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

Two dietary carcinogenicity studies have been conducted in rats with fenofibrate. In the first 24-month study, Wistar rats were dosed with fenofibrate at 10, 45, and 200 mg/kg/day, approximately 0.3, 1, and 6 times the maximum recommended human dose (MRHD), based on body surface area comparisons (mg/m²). At a dose of 200 mg/kg/day (at 6 times the MRHD), the incidence of liver carcinomas was significantly increased in both sexes. A statistically significant increase in pancreatic carcinomas was observed in males at 1 and 6 times the MRHD; an increase in pancreatic adenosomas and benign testicular interstitial cell tumors was observed at 6 times the MRHD in males. In a second 24-month rat carcinogenicity study in a different strain of rats (Sprague-Dawley), doses of 10 and 60 mg/kg/day (0.3 and 2 times the MRHD) produced significant increases in the incidence of pancreatic acinar adenomas in both sexes and increases in testicular interstitial cell tumors in males at 2 times the MRHD.

A 117-week carcinogenicity study was conducted in rats comparing three drugs: fenofibrate 10 and 60 mg/kg/day (0.3 and 2 times the MRHD), clofibrate (400 mg/kg/day; 2 times the human dose), and gemfibrozil (250 mg/kg/day; 2 times the human dose, based on mg/m² surface area). Fenofibrate increased pancreatic acinar adenomas in both sexes. Clofibrate increased hepatocellular carcinoma and pancreatic acinar adenomas in males and hepatic neoplastic nodules in females. Gemfibrozil increased hepatic neoplastic nodules in males and females, while all three drugs increased testicular interstitial cell tumors in males.

In a 21-month study in CF-1 mice, fenofibrate 10, 45, and 200 mg/kg/day (approximately 0.2, 1, and 3 times the MRHD on the basis of mg/m² surface area) significantly increased the liver carcinomas in both sexes at 3 times the MRHD. In a second 18-month study at 10, 60, and 200 mg/kg/day, fenofibrate significantly increased the liver carcinomas in male mice and liver adenomas in female mice at 3 times the MRHD.

Electron microscopy studies have demonstrated peroxisomal proliferation following fenofibrate administration to the rat. An adequate study to test for peroxisome proliferation in humans has not been done, but changes in peroxisome morphology and numbers have been observed in humans.
after treatment with other members of the fibrate class when liver biopsies were compared before and after treatment in the same individual.

**Mutagenesis**
Fenofibrate has been demonstrated to be devoid of mutagenic potential in the following tests: Ames, mouse lymphoma, chromosomal aberration and unscheduled DNA synthesis in primary rat hepatocytes.

**Impairment of Fertility**
In fertility studies rats were given oral dietary doses of fenofibrate, males received 61 days prior to mating and females 15 days prior to mating through weaning which resulted in no adverse effect on fertility at doses up to 300 mg/kg/day (~10 times the MRHD, based on mg/m² surface area comparisons).

### 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**

<table>
<thead>
<tr>
<th>IATA/ICAO - Not Regulated</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>IATA Proper shipping Name</td>
<td>N/A</td>
</tr>
<tr>
<td>IATA UN/ID No</td>
<td>N/A</td>
</tr>
<tr>
<td>IATA Hazard Class</td>
<td>N/A</td>
</tr>
<tr>
<td>IATA Packaging Group</td>
<td>N/A</td>
</tr>
<tr>
<td>IATA Label</td>
<td>N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IMDG - Not Regulated</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>IMDG Proper shipping Name</td>
<td>N/A</td>
</tr>
<tr>
<td>IMDG UN/ID No</td>
<td>N/A</td>
</tr>
<tr>
<td>IMDG Hazard Class</td>
<td>N/A</td>
</tr>
<tr>
<td>IMDG Flash Point</td>
<td>N/A</td>
</tr>
<tr>
<td>IMDG Label</td>
<td>N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DOT - Not Regulated</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>DOT Proper shipping Name</td>
<td>N/A</td>
</tr>
<tr>
<td>DOT UN/ID No</td>
<td>N/A</td>
</tr>
<tr>
<td>DOT Hazard Class</td>
<td>N/A</td>
</tr>
<tr>
<td>DOT Flash Point</td>
<td>N/A</td>
</tr>
<tr>
<td>DOT Packing Group</td>
<td>N/A</td>
</tr>
<tr>
<td>DOT Label</td>
<td>N/A</td>
</tr>
</tbody>
</table>
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

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 MSDS.