Material Safety Data Sheet

1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

Material: Mefenamic Acid Capsules USP, 250 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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<tr>
<td>Mefenamic Acid USP</td>
<td>61-68-7</td>
<td>250 mg</td>
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3. HAZARD IDENTIFICATION

Fire and Explosion
Expected to be non-combustible

Health
Mefenamic acid capsules are contraindicated in patients with known hypersensitivity to mefenamic acid.

Mefenamic acid capsules should not be given to patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients.

Environment
No information is available about the potential of this product to produce adverse environmental effects.
4. FIRST AID MEASURE

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
Symptoms following acute NSAIDs overdoses are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Hypertension, acute renal failure, respiratory depression and coma may occur, but are rare. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAIDs, and may occur following an overdose.

Patients should be managed by symptomatic and supportive care following an NSAID overdose. There are no specific antidotes. Emesis and/or activated charcoal (60 to 100 g in adults, 1 to 2 g/kg in children) and/or osmotic cathartic may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large overdose (5 to 10 times the usual dose). Forced diuresis, alkalization of urine, hemodialysis, or hemoperfusion may not be useful due to high protein binding.

5. FIRE FIGHTING MEASURE

Fire and Explosion Hazards
Assume that this product is capable of sustaining combustion.
6. ACCIDENTAL RELEASE MEASURES

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.

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].

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.
9. PHYSICAL AND CHEMICAL PROPERTIES

Physical Form

Mefenamic Acid Capsules USP, 250 mg are available as size ‘1’ capsules having ivory cap and ivory body imprinted with “LU” on cap and “R31” on body in black ink, containing white to off white granular powder.

They are supplied as follows:
NDC 68180-185-06 Bottles of 30’s
NDC 68180-185-01 Bottles of 100’s
NDC 68180-185-13 24 (3 x 8) unit dose capsules.

10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

11. TOXICOLOGICAL INFORMATION

Teratogenic Effects

Pregnancy Category C: Reproductive studies conducted in rats and rabbits have not demonstrated evidence of developmental abnormalities. However, animal reproduction studies are not always predictive of human response. There are no adequate or well controlled studies in pregnant women. Mefenamic acid should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects

Because of the known effects of nonsteroidal anti-inflammatory drugs on the fetal cardiovascular system (closure of ductus arteriosus), use during pregnancy (particularly late pregnancy) should be avoided.

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
- 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

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.