

# MATERIAL SAFETY DATA SHEET

## 1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

<b>Material</b>	<b>Nabumetone Tablets USP 500 mg and 750 mg</b>
<b>Manufacturer</b>	Lupin Limited Goa 403 722 INDIA
<b>Distributor</b>	Lupin Pharmaceuticals, Inc. Harborplace Tower, 21 <sup>st</sup> 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

<b>Ingredients</b>	<b>CAS</b>	<b>Quantity</b>
Nabumetone	42924-53-8	500 mg and 750mg

## 3. HAZARD IDENTIFICATION

<b>Fire and Explosion</b>	Expected to be non-combustible
<b>Health</b>	<p>Nabumetone tablets are contraindicated in patients with known hypersensitivity to nabumetone or product excipients.</p> <p>Nabumetone tablets 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.</p> <p>Nabumetone tablets are contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.</p>
<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects.

## 4. FIRST AID MEASURE

<b>Ingestion</b>	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.
<b>Inhalation</b>	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
<b>Skin Contact</b>	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.
<b>Eye Contact</b>	Flush eyes with plenty of water. Get medical attention.

### NOTES TO HEALTH PROFESSIONALS

<b>Medical Treatment</b>	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.
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### 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 a NSAIDs overdose. There are no specific antidotes. Emesis and/or activated charcoal (60 to 100 grams 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.

There have been overdoses of up to 25 grams of nabumetone reported with no long-term sequelae following standard emergency treatment (i.e., activated charcoal, gastric lavage, IV H<sub>2</sub>-blockers, etc.).

## 5. FIRE FIGHTING MEASURE

<b>Fire and Explosion Hazards</b>	Assume that this product is capable of sustaining combustion.
<b>Extinguishing Media</b>	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
<b>Special Firefighting Procedures</b>	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.
<b>Hazardous Combustion Products</b>	Hazardous combustion or decomposition products are expected when the product is exposed to fire.

## 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions</b>	Wear protective clothing and equipment consistent with the degree of hazard.
<b>Environmental Precautions</b>	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
<b>Clean-up Methods</b>	Collect and place it in a suitable, properly labeled container for recovery or disposal.

## 7. HANDLING AND STORAGE

<b>Handling</b>	No special control measures required for the normal handling of this product.  Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).
<b>Storage</b>	Store at 25°C (77°F); excursions permitted to 15°-30°C (59°- 86°F) [see USP Controlled Room Temperature]. Preserve in well-closed containers.

## 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

Nabumetone Tablets USP, 500 mg are available as white to off white, oval shaped, biconvex film-coated tablets debossed with "LU" on one side and "V01" on the other side.

They are supplied as follows:

NDC 68180-141-01

Bottles of 100's

NDC 68180-141-03

Bottles of 1000's

Nabumetone Tablets USP, 750 mg are available as white to off white, oval shaped, biconvex film-coated tablets debossed with "LU" on one side and "V02" on the other side.

They are supplied as follows:

NDC 68180-142-01

Bottles of 100's

NDC 68180-142-03

Bottles of 1000's

## 10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

## 11. TOXICOLOGICAL INFORMATION

### Carcinogenesis, Mutagenesis:

In 2 year studies conducted in mice and rats, nabumetone had no statistically significant tumorigenic effect. Nabumetone did not show mutagenic potential in the Ames test and mouse micronucleus test in vivo; however, nabumetone- and 6MNA-treated lymphocytes in culture showed chromosomal aberrations at 80 mcg/mL and higher concentrations (equal to the average human exposure to nabumetone at the maximum recommended dose).

### Impairment of Fertility:

Nabumetone did not impair fertility of male or female rats treated orally at doses of 320 mg/kg/day (1,888 mg/m<sup>2</sup>) before mating.

## 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.