

**Safety Data Sheet**  
**Meloxicam tablets**

**Strength:** 7.5 mg and 15 mg

**Pack Size:** 90, 100 and 500 Tablets per bottle

**Revision No.:** 02

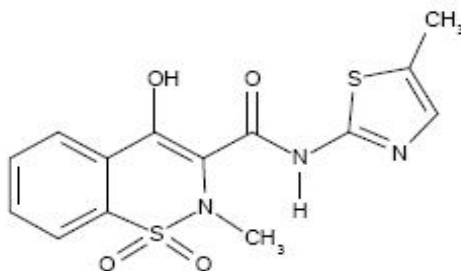
**EMERGENCY OVERVIEW**

Each Meloxicam Tablets intended for oral administration contains Meloxicam and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

**Section 1. Identification**

**Identification of the product**

**Product name:** Meloxicam Tablets  
**Formula:** C<sub>14</sub>H<sub>13</sub>N<sub>3</sub>O<sub>4</sub>S<sub>2</sub>  
**Chemical Name:** 4-hydroxy-2-methyl-N-(5-methyl-2-thiazolyl)-2H-1,2-benzothiazine-3-carboxamide-1,1-dioxide



**Manufacturer / supplier identification**

**Company:** Cadila Healthcare Ltd. Ahmedabad, India  
**Address:** Sarkhej – Bavla. N.H. 8A, Moraiya. Tal. Sanand.  
Dist. Ahmedabad – 382210. State: Gujarat. India  
**Contact for information:** Tel.: +91 79 6868100 Fax: +91 79 3750319  
**Emergency Telephone No.** Tel.: +91 79 6868100  
**Recommended use /  
Therapeutic Category** Non-steroidal anti-inflammatory drugs (NSAIDs)  
**Restriction on Use /  
Contraindications:** Meloxicam tablets are contraindicated in patients with known

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hypersensitivity to meloxicam.

Meloxicam 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.

## **Section 2. Hazard(s) Information**

### **Dose and**

#### **Administration**

For the relief of the signs and symptoms of osteoarthritis the recommended starting and maintenance oral dose of meloxicam tablets is 7.5 mg once daily. Some patients may receive additional benefit by increasing the dose to 15 mg once daily. The maximum recommended daily oral dose of meloxicam tablets is 15 mg regardless of formulation. Meloxicam tablets may be taken without regard to timing of meals.

### **Adverse Effects**

#### **Body as a Whole**

Allergic reaction, anaphylactoid reactions including shock, face edema, fatigue, fever, hot flushes, malaise, syncope, weight decrease, weight increase.

#### **Cardiovascular**

angina pectoris, cardiac failure, hypertension, hypotension, myocardial infarction, vasculitis.

#### **Central and Peripheral Nervous System**

convulsions, paresthesia, tremor, vertigo

#### **Hematologic**

agranulocytosis, leukopenia, purpura, thrombocytopenia

#### **Liver and Biliary System**

ALT increased, AST increased, bilirubinemia, GGT increased, hepatitis, jaundice, liver failure

#### **Metabolic and Nutritional**

dehydration

#### **Psychiatric Disorders**

abnormal dreaming, anxiety, appetite increased, confusion, depression, nervousness, somnolence.

#### **Respiratory**

asthma, bronchospasm, dyspnea

**Skin and Appendages**

alopecia, angioedema, bullous eruption, erythema multiforme, photosensitivity reaction, pruritus, exfoliative dermatitis, Stevens-Johnson syndrome, sweating increased, toxic epidermal necrolysis, urticaria

**Special Senses**

abnormal vision, conjunctivitis, taste perversion, Tinnitus.

**Urinary System**

albuminuria, BUN increased, creatinine increased, hematuria, interstitial nephritis, renal Failure.

**Over Dose Effect**

Symptoms following acute NSAID overdose are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Severe poisoning may result in hypertension, acute renal failure, hepatic dysfunction, respiratory depression, coma, convulsions, cardiovascular collapse, and cardiac arrest. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAIDs, and may occur following an overdose.

**Medical Conditions**

Following Medical condition are,

- Serious and potentially fatal cardiovascular (CV) thrombotic events, myocardial infarction, and stroke. Patients with known CV disease/risk factors may be at greater risk.
- Serious gastrointestinal (GI) adverse events which can be fatal. The risk is greater in patients with a prior history of ulcer disease or GI bleeding, and in patients at higher risk for GI events, especially the elderly.
- Elevated liver enzymes, and rarely, severe hepatic reactions. Discontinue use immediately if abnormal liver enzymes persist or worsen.
- New onset or worsening of hypertension. Blood pressure should be monitored closely during treatment.
- Fluid retention and edema. Should be used with caution in patients with fluid retention or heart failure.
- Renal papillary necrosis and other renal injury with long-term use. Use with caution in the elderly, those with impaired renal function, heart failure, liver dysfunction, and those taking diuretics, ACE-inhibitors, or angiotensin II antagonists. The use of meloxicam in patients with severe renal impairment is not recommended.
- Serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal and can occur without warning. Discontinue meloxicam at first appearance of rash or skin reactions.

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<b>Contraindications</b>	Meloxicam tablets are contraindicated in patients with known hypersensitivity to meloxicam.  Meloxicam 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.
<b>Pregnancy Comments</b>	In late pregnancy, as with other NSAIDs, meloxicam tablets should be avoided because it may cause premature closure of the ductus arteriosus.
<b>Pregnancy Category</b>	NA

**Section 3. Composition / information on ingredients**

<b>Component</b>	<b>Exposure Limit</b>	<b>CAS No.</b>
<b>Principle Component :</b>		
Meloxicam 7.5mg and 15mg	Not Found	71125-38-7
<b>Inactive Ingredients</b>		
Colloidal silicon dioxide	Not Found	7631-86-9
Crospovidone	Not Found	9003-39-8
Lactose monohydrate	Not Found	10039-26-6
Magnesium stearate	Not Found	557-04-6
Microcrystalline cellulose	Not Found	9004-34-6
Povidone	Not Found	9003-39-8
Sodium citrate dihydrate	Not Found	6132-04-3

**Section 4. First - aid measures**

<b>General</b>	Remove from exposure. Remove contaminated Clothing. Person developing serious hypersensitivity reaction must receive medical attention
<b>Overdose Treatment</b>	Cholestyramine is known to accelerate the clearance of meloxicam. Patients should be managed with symptomatic and supportive care following an NSAID overdose. In cases of acute overdose, gastric lavage followed by activated charcoal is recommended. Gastric lavage performed more than one hour after overdose has little benefit in the treatment of overdose. Administration of activated charcoal is recommended for

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patients who present 1-2 hours after overdose. For substantial overdose or severely symptomatic patients, activated charcoal may be administered repeatedly.

**Section 5. Fire - fighting measures**

<b>Flash point</b>	Not Found	<b>Upper Flammable Limit:</b>	Not Found
<b>Auto-Ignition Temperature:</b>	Not Found	<b>Lower Flammable Limit:</b>	Not Found
<b>Extinguishing Media</b>	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.	<b>Fire and Explosion Hazard</b>	This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build-up of static electricity.
<b>Fire Fighting Procedure</b>	As with all fires, evacuate personnel to a safe area. Fire fighter should use self- contained breathing equipment and protective clothing.		

**Section 6. Accidental Release Measures**

<b>Spill Response</b>	Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.
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**Section 7. Handling and Storage**

<b>Storage</b>	Store at 20° to 25°C (68° to 77°F) in dry place. Dispense in a tight, light-resistant container.
<b>Incompatibilities:</b>	No data available.

**Section 8. Exposure controls / personal protection**

<b>Respiratory Protection</b>	Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.
<b>Skin Protection</b>	Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.

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<b>Eye protection</b>	Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.
<b>Protective Clothing</b>	Protective clothing is not normally necessary, however it is good practice to use apron.
<b>Engineering Control</b>	Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

**Section 9. Physical and chemical properties**

<b>Appearance</b>	Meloxicam Tablets, 7.5 mg are yellow, round-shaped, flat beveled edge, uncoated tablets debossed with 'ZC' and '25' on one side and plain on other side.  Meloxicam Tablets, 15 mg are yellow, round-shaped, flat beveled edge, uncoated tablet debossed with 'ZC' and '26' on one side and plain on other side.		
<b>Solubility in water</b>	No Data Available	<b>Odour</b>	Odourless
<b>Boiling point</b>	No Data Available	<b>Melting Point</b>	No Data Available
<b>Evaporation rate</b>	No Data Available	<b>Vapour density</b>	No Data Available
<b>Reactivity in water</b>	No Data Available	<b>Evaporation rate</b>	No Data Available
<b>% Volatile by volume</b>	No Data Available	<b>Specific gravity</b>	No Data Available
		<b>Vapour pressure</b>	No Data Available
<b>Other information</b>	Meloxicam is a pale yellow powder, practically insoluble in water, slightly soluble in acetone, soluble in dimethylformamide, very slightly soluble in ethanol (96 %) and in methanol.		

**Section 10. Stability and Reactivity**

<b>Condition to avoid</b>	Avoid exposure to extreme heat, light and moisture.	<b>Stable</b>	Stable under normal ambient and anticipated storage and handling conditions.
<b>Decomposition Products</b>	No Data Available	<b>Hazardous Reaction</b>	No data available.
<b>Incompatibilities:</b>	No data available.		

**Section 11. Toxicological information**

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<b>General</b>	Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.
<b>Target organ</b>	Eye contact, Skin contact and inhalation is not great risk as this product is tablet.
<b>Other</b>	Not Available

**Section 12. Ecological information**

Do not allow product to enter drinking water supplies, waste water or soil

**Section 13. Disposal Consideration**

Dispose the waste in accordance with all applicable Federal, State and local laws.

**Section 14. Transport Information**

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).

**Section 15. Regulatory Information**

Generic Medicine. Approved by USFDA & the ANDA Number is 077921

**Section 16. Other information**

None

**Date of issue:** 28/05/2015

**Supersedes edition of:** 01

The information contained herein is based on the state of our knowledge. It Characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.