Material Safety data sheet

MELOXICAM TABLETS

Strength: 7.5 mg and 15 mg **Pack Size:** 90, 100 and 500 Tablets per bottle **Revision No.:** 00

EMERGENCY OVERVIEW

MELOXICAM TABLETS contain 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 of the substance

Identification of the product

Product name:	Meloxicam Tablets
Formula:	$C_{14}H_{13}N_3O_4S_2$
Chemical Name:	4-hydroxy-2-methyl-*N*-(5-methyl-2-thiazolyl)-2*H*-1,2-benzothiazine-3-carboxamide-1,1-dioxide
Therapeutic Category	Non-steroidal anti-inflammatory drugs (NSAIDs)

Manufacturer / supplier identification

Company:	**Cadila Healthcare Ltd. Ahmedabad, India**
Contact for information:	Tel.: +91 79 6868100 Fax: +91 79 3750319
Emergency telephone No.	Tel.: +91 79 6868100

Section 2. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component :		
Meloxicam, 7.5 mg and 15mg	Not Found	71125-38-7
Inactive Ingredients :		
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 3. Health Hazards 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
Gastrointestinal	colitis, dry mouth, duodenal ulcer, eructation, esophagitis, gastric ulcer, gastritis, gastroesophageal reflux, gastrointestinal hemorrhage, hematemesis, hemorrhagic duodenal ulcer, hemorrhagic gastric ulcer, intestinal perforation, melena, pancreatitis, perforated duodenal ulcer, perforated gastric ulcer, stomatitis ulcerative
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.
Contraindications	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.
Pregnancy Comments	In late pregnancy, as with other NSAIDs, meloxicam tablets should be avoided because it may cause premature closure of the ductus arteriosus.
Pregnancy Category	**NA**

Section 4. First aid measures

General	Remove from exposure. Remove contiminated Clothing. Person devloping serious hypersensitivity reaction must receive medical attention
Overdose Treatment	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 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

Flash point	Not Found	**Upper Flammable Limit:**	Not Found
Auto-Ignition Temperature:	Not Found	**Lower Flammable Limit:**	Not Found
Extinguishing Media	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.	**Fire and Explosion Hazard**	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.

Fire Fighting Procedure	As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.

Section 6. Storage / Spill / Disposal Measures

Storage	Store at 20°-25°C (68°-77°F) in dry place. Dispense in a tight, light-resistant container.
Spill Response	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.
Disposal	Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 7. Exposure controls and personal protection

Respiratory Protection	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.
Skin Protection	Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.
Eye protection	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.
Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.

Section 8. Physical and chemical properties

Appearance

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.

Odour	Odourless	**Melting Point**	No Data Available
Solubility in water	No Data Available	**Vapour density**	No Data Available
Boiling point	No Data Available	**Evaporation rate**	No Data Available
Evaporation rate	No Data Available	**Specific gravity**	No Data Available
Reactivity in water	No Data Available	**Vapour pressure**	No Data Available
% Volatile by volume	No Data Available		

Other information 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 9. Physical Hazards

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

Section 10. Toxicological information

Handling of formulated product is not expected to cause any adverse affects. The data pertains to the ingredient in formulations, rather than this specie formulation.

Target organ	Eye contact, Skin contact and inhalation is not great risk as this product is tablet.
other	There is limited experience with meloxicam overdose. Four cases have taken 6 to 11 times the highest recommended dose; all recovered.

Section 11. Ecological information

No data available on Ecotoxicity

Section 12. Other information

None

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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.