



HETERO LABS LIMITED

"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018. A.P., INDIA.
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250
e-mail : contact@heterodrugs.com URL : http://www.heterodrugs.com

SAFETY DATA SHEET

Section 1: Identification	
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Material	Montelukast Sodium Chewable Tablets
Manufacturer	Hetero labs limited, Unit V, Polepally, Jadcherla Mahaboob Nagar-509 301, India.
Distributor	Camber Pharmaceuticals, Inc, Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Hazard statement	This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.
Adverse Effects	Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice. In the following description of clinical trials experience, adverse reactions are listed regardless of causality assessment. The most common adverse reactions (incidence $\geq 5\%$ and greater than placebo; listed in descending order of frequency) in controlled clinical trials were: upper respiratory infection, fever, headache, pharyngitis, cough, abdominal pain, diarrhea, otitis media, influenza, rhinorrhea, sinusitis, otitis.
Contraindications	Hypersensitivity to any component of this product.
Section 3: Composition/Information on Ingredients	
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Ingredients	CAS 151767-02-1
Montelukast Sodium USP	
Section 4: First-Aid Measures	
Section 4, First-aid measures	
General	Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately. Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention. Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately. Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.



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Section 5: Fire-Fighting Measures	
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Extinguishing Media	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products	Formation of toxic gases is possible during heating or fire.
Fire Fighting Procedures:	During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus
Fire / Explosion Hazards	Fine particles (such as dust and mists) may fuel fires/explosions
Section 6: Accidental Release Measures	
Section 6, Accidental release measures	
Health and Safety Precautions	Personnel involved in clean-up should wear appropriate personal protective equipment.
Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.
Section 7: Handling and Storage	
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Storage	Store at 20° to 25° C (68° to 77° F) [see USP Controlled Room Temperature].
Section 8: Exposure Controls/Personal Protection	



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Montelukast sodium

Manufacturer OEB: OEB3 (control exposure to the range of >10ug/m³ to < 100ug/m³)

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airbornecontamination levels below the exposure limits listed above in this section.

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate

respirator with a protection factor sufficient to control exposures to below the OEL.

Section 9: Physical and Chemical Properties

Section 9, Physical and chemical properties

Physical Form

Montelukast Sodium 4-mg (equivalent to 4-mg montelukast) Chewable Tablets are light pink colored, speckled, oval, biconvex shaped, chewable tablets debossed with 'I' on one side and '112' on the other side. They are supplied as follows:

Bottles of 30 tablets	NDC 31722-727-30
Bottles of 100 tablets	NDC 31722-727-01
Bottles of 1000 tablets	NDC 31722-727-10
Blister card of 10 Unit-dose tablets	NDC 31722-727-31
Blister pack of 100 (10 x 10) Unit-dose tablets	NDC 31722-727-32
Bottles of 90 tablets	NDC 31722-727-90

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Section 10: Stability and Reactivity

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Stable under recommended storage conditions.

Section 11: Toxicological Information

General Information:

Information on likely routes of exposure

Inhalation: Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Inhalation of dusts may cause respiratory irritation.

Skin contact: Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Dust may irritate skin.

Eye contact : Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Dust may irritate the eyes.

Ingestion : Health injuries are not known or expected under normal use.

Symptoms related to the physical, chemical and toxicological characteristics : Most common side effects are upper respiratory infection, fever, headache, pharyngitis, cough, abdominal pain, diarrhea, otitis media, influenza, rhinorrhea, sinusitis, otitis.

Information on toxicological effects

Acute toxicity May be harmful if swallowed in large quantities.

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Serious eye damage/eye irritation :

Direct contact with eyes may cause temporary irritation.

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization This product is not expected to cause skin sensitization.

Germ cell mutagenicity Not expected to be mutagenic.

Carcinogenicity This product is not considered to be a carcinogen by NTP, IARC, or OSHA.

Reproductive toxicity

Because there are no adequate and well-controlled studies in pregnant women, this drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Pregnancy Category B

It is not known whether this product is excreted in human milk. Because many drugs are excreted

in human milk, caution should be exercised when administering to a nursing woman

Aspiration hazard Due to the physical form of the product it is not an aspiration hazard.

Section 12: Ecological Information

Environmental Overview:

Environmental properties have not been investigated. Releases to the environment should be avoided.



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Section 13: Disposal Considerations

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: Transport Information

Note - not classified by transport regulations, proper shipping name non-regulated

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.

Hetero labs limited shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero labs limited reserves the right to revise this MSDS.