



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

Product Name	Maraviroc Tablets 150 mg/300 mg.
Recommended use	In combination with other medicines, in the treatment of the infection caused by the human immunodeficiency virus (HIV).
Manufacturer	Hetero Labs Limited Unit III 22-110, Part-II, IDA, Jeedimetla, Hyderabad-500 055, Telangana, India.
Distributor	Camber Pharmaceuticals, Inc. , Piscatway, NJ 08854

Section 2: Hazard(s) Identification

Statement of Hazard:	May cause damage to cardiovascular system through prolonged or repeated exposure.
Additional Hazard Information:	
Short Term:	May produce slight eye irritation. if tablets are crushed or broken (based on components)
Long Term:	Repeat-dose studies in animals have shown a potential to cause adverse effects on liver.
Known Clinical Effects:	Adverse effects most commonly reported in clinical use include diarrhea, headache, nausea, vomiting, dizziness, insomnia and skin rash.

Section 3: Composition/Information On Ingredients

Ingredient	Maraviroc Amorphous
CAS	376348-65-1

Section 4: First-Aid Measures

Description of first aid measures	
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.
Skin Contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Eye Contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately



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Section 5: Fire-Fighting Measures

Extinguishing Media(suitable)	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	Formation of toxic gases is possible during heating or fire. Emits toxic fumes of oxides of nitrogen, carbon monoxide, carbon dioxide, and halogen-containing gases.
Fire Fighting Procedures:	During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus.

Section 6: Accidental Release Measures

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.
Measures for Cleaning / Collecting:	Contain the source of the spill if it is safe to do so. Avoid generating airborne dust. Collect spilled material by a method that controls dust generation.
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

General Handling:	Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment. Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
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Storage	Store as directed by product packaging.
Section 8: Exposure Controls/Personal Protection	
Analytical Method:	Analytical method available for Maraviroc. Contact Pfizer Inc. for further information
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 airborne contamination levels below the exposure limits listed above in this section.
Section 9: Physical and Chemical Properties	
Physical Form	film coated tablets
	150 mg: White to off-white colored, oval, biconvex, film coated tablets debossed with 'J' on one side and '62' on the other side. Bottle of 60 tablets NDC 31722-579-60
	300 mg: White to off-white colored, oval, biconvex, film coated tablets debossed with 'J' on one side and '63' on the other side. Bottle of 60 tablets NDC 31722-580-60
Section 10: Stability and Reactivity	
Chemical stability	Stable under normal conditions of use.
Conditions to avoid	Keep away from heat and other sources of ignition, including electrostatic discharge.
Incompatible materials	As a precautionary measure, keep away from strong oxidizers.
Section 11: Toxicological Information	
General Information	The information included in this section describes the potential hazards of the individual ingredients.



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Section 12: Ecological Information

No harmful effects to aquatic organisms are expected. This material has low potential to bioaccumulate and long-term adverse effects to aquatic organisms are not expected. No toxicity to wastewater treatment microorganisms is expected. Releases to the environment should be avoided.

Section 13: Disposal Considerations

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

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Section 15: Regulatory Information

May cause damage to cardiovascular system through prolonged or repeated exposure.

Section 16: Other Information

Issue Date : 12-01-2022

Version : 00

Further information

Revision date: New issue

Revision note: New issue

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. 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.

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