Chemical Research and Development

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MATERIAL SAFETY DATA SHEET

[CAUTION: The identity of this substance may be proprietary to Starks Associates, Inc. and to National Institute of Allergy and Infectious Diseases]

----------IDENTIFICATION----------

Chemical Name: 4-Pyrimidinecarboxamide, N-[(4-fluorophenyl)-methyl]-1,6-dihydro-5-hydroxy-1-methyl-2-[1-methyl-1-[[(5-methyl-1,3,4-oxadiazol-2-yl)carbonyl]amino]-ethyl]-6-oxo-, potassium salt (1:1)

Other Names: Isentress™; raltegravir potassium

Starks Reference No: NG1-44-1

Chemical Formula: $C_{20}H_{20}FKN_6O_5$

----------CAS REGISTRY NUMBERS----------

CAS#: 871038-72-1

----------HEALTH HAZARD DATA----------

See the attached first page of the FDA-approved product label for Isentress™ (raltegravir potassium). The complete product label is found at the following web address:

http://www.fda.gov/cder/foi/label/2007/022145lbl.pdf

----------PRIMARY ROUTE(S) OF ENTRY (Accidental Exposure)--------

No applicable information was found; prevent all accidental exposure to skin, eyes, or lungs.

----------PHYSICAL AND CHEMICAL CHARACTERISTICS----------

White powder; melting point 280-282°C (d)(uncorrected); soluble in water, DMSO; insoluble in CH_3CN, EtOH.

PHYSICAL HAZARDS

No applicable information was found; as with most organic powders, dust explosion may be possible when powder is suspended in air.

EXPOSURE LIMIT

No specifically applicable information was found; advisable to avoid exposure to skin, eyes or lungs.

NTP, IARC, OSHA

No entries were found. To the best of our knowledge, the potential carcinogenic properties of this material are not known.

PRECAUTIONS FOR SAFE HANDLING

This product should be handled only by, or under the close supervision of, those properly qualified in the handling and use of potentially hazardous chemicals. It should be borne in mind that the toxicological and physiological properties of many compounds are not yet well defined.

Appropriate Hygiene Practices

Avoid personal contact through ingestion, inhalation, contact with eyes or skin.

Protective Measures During Repair or Maintenance of Contaminated Equipment

No applicable information was found.

Steps to be taken if material is released or spilled

Wear self-contained breathing apparatus, rubber boots and heavy rubber gloves.

Sweep up, place in a bag and hold for waste disposal.

Avoid raising dust.
Ventilate area and wash spill site after material pickup is complete.

Waste disposal method

Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Observe all federal, state & local laws.

----------CONTROL MEASURES----------

Engineering Controls

Mechanical exhaust required.

Personal Protective Equipment

Safety glasses or chemical safety goggles. Impermeable gloves and lab coat. NIOSH/MSHA approved respirator may be advisable.

----------EMERGENCY AND FIRST AID PROCEDURES----------

In case of contact, immediately flush eyes with copious amounts of water for at least 15 minutes.

In case of contact, immediately wash skin with soap and copious amount of water.

If inhaled, remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen.

Call a physician.

Wash contaminated clothing before reuse or discard.

Information contained herein is based upon observations made in the course of isolating this substance and other information available to us. We have undertaken no tests to confirm the accuracy or completeness of this information and assume no responsibility in this regard.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ISENTRESS safely and effectively. See full prescribing information for ISENTRESS.

ISENTRESS (raltegravir) Tablets
Initial U.S. Approval: 2007

INDICATIONS AND USAGE

ISENTRESS™ is a human immunodeficiency virus integrase strand transfer inhibitor (HIV-1 INSTI) indicated:

- In combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-experienced adult patients who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents (1).

The safety and efficacy of ISENTRESS have not been established in treatment-naïve adult patients or pediatric patients (1).

DOSAGE AND ADMINISTRATION

- 400 mg administered orally, twice daily with or without food (2.1).

DOSAGE FORMS AND STRENGTHS

Tablets: 400 mg (3).

CONTRAINDICATIONS

None

WARNINGS AND PRECAUTIONS

Monitor for Immune Reconstitution Syndrome (5.1)

Drug Interactions

- Caution should be used when coadministering ISENTRESS with strong inducers of uridine diphosphate glucuronosyltransferase (UGT) 1A1 (e.g., rifampin) due to reduced plasma concentrations of raltegravir (5.2).

ADVERSE REACTIONS

- The most common adverse reactions (>10%) of all intensities, reported in subjects in either the ISENTRESS or the placebo treatment group, regardless of causality were: nausea, headache, diarrhea and pyrexia (6.1).
- Creatine kinase elevations were observed in subjects who received ISENTRESS. Myopathy and rhabdomyolysis have been reported; however, the relationship of ISENTRESS to these events is not known. Use with caution in patients at increased risk of myopathy or rhabdomyolysis, such as patients receiving concomitant medications known to cause these conditions (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Merck & Co., Inc. at 1-877-888-4231 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS

Pregnancy:

- ISENTRESS should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Physicians are encouraged to register pregnant women exposed to ISENTRESS by calling 1-800-258-4263 so that Merck can monitor maternal and fetal outcomes (8.1).

Nursing Mothers:

- Breast-feeding is not recommended while taking ISENTRESS (8.3).

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 10/2007

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the Full Prescribing Information are not listed.