

SAFETY DATA SHEET



EDURANT

| | | | |
|----------------|------------------------------|-----------------------------|---|
| Version 9.0 | Revision Date: 2025/09/10 | SDS Number: 100000010319 | Date of last issue: 2025/02/23 Date of first issue: 2014/05/12 |
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SECTION 1. IDENTIFICATION

| | | |
|----------------|---|---|
| Product name | : | EDURANT |
| Substance name | : | EDURANT 25 mg FC tablets Rilpivirine Hydrochloride / TMC 278 |

Manufacturer or supplier's details

| | | |
|--|---|--|
| Company name of supplier | : | Janssen Pharmaceuticals, Inc. |
| Address | : | 1125 Trenton-Harbourton Rd Titusville NJ 08560 |
| | | USA |
| Telephone | : | +16097302000 |
| E-mail address of person responsible for the SDS | : | SDSJanssen@its.jnj.com |
| Emergency telephone number | : | CHEMTREC US: 1-800-424-9300 CHEMTREC International: +1 703-741-5970 |

Recommended use of the chemical and restrictions on use

| | | |
|-----------------|---|--|
| Recommended use | : | Finished Pharmaceutical Product Pharmacotherapeutic group: Antivirals for systemic use This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component. This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200). |
|-----------------|---|--|

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

| | | |
|----------------|---|-------------|
| Eye irritation | : | Category 2A |
|----------------|---|-------------|

GHS label elements

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Hazard pictograms :



Signal word :

Warning

Hazard statements :

H319 Causes serious eye irritation.

Precautionary statements :

Prevention:

P264 Wash skin thoroughly after handling.
P280 Wear eye protection/ face protection.

Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

Other hazards

Refer to the pharmacotherapeutic group (section 1.2) and the patient packaging insert to evaluate the possible workplace hazards when this Finished Pharmaceutical Product is accidentally leaking, broken or crushed.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture :

Mixture

Chemical nature :

Solid

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|-----------------------------------|-------------|-----------------------|
| RILPIVIRINE HYDROCHLORIDE | 700361-47-3 | >= 20 - < 30 |
| Octadecanoic acid, magnesium salt | 557-04-0 | >= 10 - < 20 |
| titandioxide | 13463-67-7 | >= 1 - < 5 |

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

If inhaled :

Health injuries are not known or expected under normal use.
If breathed in, move person into fresh air.
Consult a physician.

In case of skin contact :

Take off contaminated clothing and shoes immediately.
Wash off with soap and water.
If symptoms persist, call a physician.

In case of eye contact :

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

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Remove contact lenses.
Consult a physician.

If swallowed : If swallowed, rinse mouth with water (only if the person is conscious).
Call a physician immediately.

Most important symptoms and effects, both acute and delayed : Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.
Abdominal pain
Dizziness
headache
insomnia
Rash
depression

Notes to physician : Treat symptomatically.
Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Hazardous combustion products : No information available.

Further information : No information available.

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.

Environmental precautions : Should not be released into the environment.

Methods and materials for containment and cleaning up : Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".
Large spills: Sweep up (intact) or vacuum with HEPA filter (broken or crushed) or via wet cleaning into suitable containers for disposal. Pick up and arrange without creating dust. Keep in properly labelled containers.
Small spills: Moisten a towel, cover the spill, pick up the spill or use HEPA vacuum.

SECTION 7. HANDLING AND STORAGE

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Advice on protection against fire and explosion : No data available

Advice on safe handling : To avoid thermal decomposition, do not overheat. Avoid inhalation, ingestion and contact with skin and eyes. Do not break, crush or spill this Finished Pharmaceutical Product. Use personal protective equipment as required.

Conditions for safe storage : To maintain product quality, do not store in heat or direct sunlight. Store in original container. Keep containers tightly closed in a cool, well-ventilated place. Keep away from heat and sources of ignition. Keep locked up. Protect against light.

Recommended storage temperature : 59 - 86 °F / 15 - 30 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---|-------------|--|---|-------------------|
| RILPIVIRINE HYDROCHLORIDE | 700361-47-3 | TWA | 0.180 mg/m3 | J&J OEL/PBOEL HHC |
| | | PBOEL-HHC | 1 B | J&J OEL/PBOEL HHC |
| Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 1B. | | | | |
| Octadecanoic acid, magnesium salt | 557-04-0 | TWA (Inhalable particulate matter) | 10 mg/m3 | ACGIH |
| | | TWA (Respirable particulate matter) | 3 mg/m3 | ACGIH |
| titandioxide | 13463-67-7 | TWA | 2.4 mg/m3 | J&J OEL/PBOEL HHC |
| | | TWA | 10 mg/m3 | ACGIH |

Engineering measures : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.

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If this product is processed not in accordance with the prescribed use, contact the Industrial Hygiene / Environment Health Safety Expert to assess the situation.

Validated Industrial Hygiene Analytical methods are developed to monitor and quantify inhalable exposure to the Active Pharmaceutical Ingredient. For more information contact Bureau Veritas Laboratories - Lake Zurich (BV_LZLab@bureauveritas.com) or the Laboratory of Occupational and Environmental Hygiene (lamh.be).

Personal protective equipment

| | |
|--------------------------|--|
| Respiratory protection | : No personal respiratory protective equipment normally required. |
| Hand protection | |
| Remarks | : Disposable gloves |
| Eye protection | : No special precautions required. |
| Skin and body protection | : closed work clothing |
| Protective measures | : The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if necessary. |
| Hygiene measures | : Handle in accordance with good industrial hygiene and safety practice. |

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|-----------------------------|-----------------------------|
| Appearance | : tablet, Coated |
| Colour | : white |
| Odour | : No data available |
| Odour Threshold | : No data available |
| pH | : No data available |
| Melting point/ range | : No data available |
| Boiling point/boiling range | : No data available |
| Flash point | : No data available |
| Evaporation rate | : No data available |
| Flammability (solid, gas) | : No information available. |

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| | |
|--|---------------------|
| Self-ignition | : No data available |
| Upper explosion limit / Upper flammability limit | : No data available |
| Lower explosion limit / Lower flammability limit | : No data available |
| Vapour pressure | : No data available |
| Relative vapour density | : No data available |
| Relative density | : No data available |
| Density | : No data available |
| Solubility(ies) | |
| Water solubility | : No data available |
| Partition coefficient: n-octanol/water | : No data available |
| Decomposition temperature | : No data available |
| Viscosity | |
| Viscosity, dynamic | : Not applicable |
| Viscosity, kinematic | : Not applicable |
| Explosive properties | : No data available |
| Oxidizing properties | : No data available |

SECTION 10. STABILITY AND REACTIVITY

| | |
|------------------------------------|---|
| Reactivity | : None reasonably foreseeable. |
| Chemical stability | : Stable under recommended storage conditions. |
| Possibility of hazardous reactions | : No dangerous reaction known under conditions of normal use. |
| Conditions to avoid | : Exposure to light. |
| Incompatible materials | : None known. |

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

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Acute oral toxicity : Acute toxicity estimate: 2,080 mg/kg
Method: Calculation method

Components:

RILPIVIRINE HYDROCHLORIDE:

Acute oral toxicity : LD50 (Rat): > 800 mg/kg
Remarks: May be harmful if swallowed.

LD50 (Dog): > 80 mg/kg

Acute inhalation toxicity : Remarks: May be harmful if inhaled.

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

Components:

RILPIVIRINE HYDROCHLORIDE:

Result : Eye irritation
Method : In vitro BCOP (Bovine Corneal Opacity and Permeability) assay

Respiratory or skin sensitisation

Components:

RILPIVIRINE HYDROCHLORIDE:

Method : Local Lymph Node Assay (LLNA) in mice
Result : Not a sensitizer

Germ cell mutagenicity

Components:

RILPIVIRINE HYDROCHLORIDE:

Genotoxicity in vitro : Test Type: Ames test
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: in vivo assay
Cell type: Bone marrow
Method: Mutagenicity (micronucleus test)
Result: negative

Carcinogenicity

Components:

RILPIVIRINE HYDROCHLORIDE:

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| | |
|-------------|---|
| Remarks | : No data available |
| IARC | No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. |
| OSHA | No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens. |
| NTP | No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP. |

Reproductive toxicity

Components:

RILPIVIRINE HYDROCHLORIDE:

| | |
|-------------------------------|---|
| Effects on fertility | : Dose: 160 - 1600 Remarks: negative |
| Effects on foetal development | : Dose: 160 - 1600 mg/kg Remarks: negative |

STOT - single exposure

No data available

STOT - repeated exposure

No data available

Repeated dose toxicity

No data available

Aspiration toxicity

No data available

Experience with human exposure

No data available

Toxicology, Metabolism, Distribution

No data available

Neurological effects

No data available

Further information

No data available

Other health hazards

No data available

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SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

RILPIVIRINE HYDROCHLORIDE:

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae/aquatic plants : Remarks: No data available

Persistence and degradability

Components:

RILPIVIRINE HYDROCHLORIDE:

Biodegradability : Remarks: No data available

Bioaccumulative potential

Components:

RILPIVIRINE HYDROCHLORIDE:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : log Pow: 4.86

Octadecanoic acid, magnesium salt:

Partition coefficient: n-octanol/water : Remarks: No data available

titandioxide:

Partition coefficient: n-octanol/water : Remarks: No data available

Mobility in soil

Components:

RILPIVIRINE HYDROCHLORIDE:

Mobility : Remarks: No data available

Other adverse effects

Components:

RILPIVIRINE HYDROCHLORIDE:

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Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : In accordance with National, Federal, State and Local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

49 CFR

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 313

: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

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| | |
|---|-------------|
| alpha-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-, hydrate (1:1) | 5989-81-1 |
| RILPIVIRINE HYDROCHLORIDE | 700361-47-3 |
| Octadecanoic acid, magnesium salt | 557-04-0 |
| croscarmellose sodium | 74811-65-7 |

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California List of Hazardous Substances

| | |
|----------|-----------|
| povidone | 9003-39-8 |
|----------|-----------|

California Permissible Exposure Limits for Chemical Contaminants

| | |
|-----------------------------------|----------|
| Octadecanoic acid, magnesium salt | 557-04-0 |
|-----------------------------------|----------|

The components of this product are reported in the following inventories:

- : This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.

Other regulations

Restricted to professional users.

This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.

Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

| | |
|-------------------------|---|
| ACGIH | : US. ACGIH Threshold Limit Values |
| ACGIH | : USA. ACGIH Threshold Limit Values (TLV) |
| J&J OEL/PBOEL HHC | : J&J OEL/PBOEL HHC |
| ACGIH / TWA | : Time weighted average |
| ACGIH / TWA | : 8-hour, time-weighted average |
| J&J OEL/PBOEL HHC / TWA | : Time weighted average |
| J&J OEL/PBOEL HHC / | : PBOEL-HHC |
| PBOEL-HHC | |

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS -

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Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECL - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 2025/09/10

Date and Number Formats

This document uses the following notation for printing dates and numbers:

| | | | |
|----------|----------------|----|------------|
| Date: | Dec 31th, 2012 | as | 2012/12/31 |
| Numbers: | 123456,78 | as | 123,456.78 |

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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