

Viramune® tablets

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000010903 Date of last issue: -
Date of first issue: 06/03/2015

SECTION 1. IDENTIFICATION

Product name : Viramune® tablets

Synonyms : Active ingredient: Nevirapine <= 25 %
Viramune® 200 mg tablets, Viramune® XR 50 mg tablets,
Viramune® XR 100 mg tablets, Viramune® XR 400 mg tablets

Product code : 000000010903

Manufacturer or supplier's details

Company name of supplier : Boehringer-Ingelheim Pharmaceuticals, Incorporated

Address : 900 Ridgebury Road
Ridgefield, Connecticut
06877-0368

Emergency telephone number : +1-800-424-9300 CHEMTREC Emergency Phone Number
CHEMTREC – 24 Hours

Routine Contact Number : (203) 778-7759

Recommended use of the chemical and restrictions on use

Recommended use : Mixture for production of finished medicinal products.

Prepared by : Corp. Div. EHS & Sustainability / Global EHS Services
EHS-service@boehringer-ingelheim.com

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification (Hazard Communication Standard (HCS) 29 CFR 1910.1200)**

Acute toxicity (Oral) : Category 4

GHS Label element (Hazard Communication Standard (HCS) 29 CFR 1910.1200)

Hazard pictograms :



Signal word : Warning

Hazard statements : H302 Harmful if swallowed.

Precautionary statements : **Prevention:**
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
Response:
P301 + P312 + P330 IF SWALLOWED: Call a POISON

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CENTER or doctor/ physician if you feel unwell. Rinse mouth.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
Nevirapine	129618-40-2	< 25

SECTION 4. FIRST AID MEASURES

- General advice : Remove from exposure, lie down.
Take off immediately all contaminated clothing.
Victim to lie down in the recovery position, cover and keep him warm.
First Aid responders should pay attention to self-protection and use the recommended protective clothing
- If inhaled : Keep patient calm, remove to fresh air, seek medical attention.
- In case of skin contact : Wash off thoroughly with ample water.
Seek medical attention.
- In case of eye contact : Immediately wash affected eyes for at least 15 minutes under running water with eyelids held open, consult an eye specialist.
- If swallowed : Rinse mouth immediately and then drink plenty of water, seek medical attention.
- Most important symptoms and effects, both acute and delayed : None known.
- Notes to physician : Observe the summary of product characteristics of proprietary medicinal products

SECTION 5. FIREFIGHTING MEASURES

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

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Water
Dry chemical
Foam
Carbon dioxide (CO₂)

Specific hazards during fire-fighting : In case of fire and/or explosion do not breathe fumes.
Can be released in case of fire:
Nitrogen oxides (NO_x)
Carbon oxides

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Wear protective equipment. Keep unprotected persons away.
Ensure adequate ventilation.
Never return spills in original containers for re-use.

Environmental precautions : Do not flush into surface water or sanitary sewer system.

Methods and materials for containment and cleaning up : Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Clean-up methods - large spillage
Dampen, pick up mechanically and dispose of.
Clean-up methods - small spillage
Use approved industrial vacuum cleaner for removal.
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.
Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces.
Minimize dust generation and accumulation.
Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Breathing must be protected when large quantities are decanted without local exhaust ventilation.
Keep container closed when not in use.
Do not open until use.
Protect from moisture.

Conditions for safe storage : Store in original container.
Protect from heat and direct sunlight.
Jointless smooth floor

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Keep container tightly closed.

Materials to avoid : Keep away from food, drink and animal feedingstuffs.
Advice on Segregation

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Components with workplace control parameters**

Components	Basis	Factor	Cateryory	Values	Remark
5,6-Dihydro-11-cyclopropyl-4-methyl-6H-dipyrido[3,2-b:2',3'-e][1,4]diazepin-6-one 129618-40-2	ECL		3A	50 µg/m3	
	BIPC		1b		
ECL (BIPI Exposure Control Limit)					

Contains no substances with occupational exposure limit values.

Engineering measures : It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen deficient environment.
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).
Use only appropriately classified electrical equipment and powered industrial trucks.

Personal protective equipment

Respiratory protection : Use breathing apparatus if exposed to vapours/dust/aerosol.
half mask (EN 140)
particle filter P2

Hand protection Material : Chemical resistant gloves made of butyl rubber or nitrile rubber category III according to EN 374.
Directive : Protective gloves against chemicals and micro-organisms

Eye protection : Safety glasses with side-shields

Skin and body protection : Laboratory: laboratory coat; factory: disposable Overall.

Protective measures : Handle in accordance with good industrial hygiene and safety practice.
Do not breathe dust.
Avoid contact with skin, eyes and clothing.
Only use protective equipment in accordance with national/international regulations. Follow the national regulations

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about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.

Hygiene measures : General industrial hygiene practice.
Wash hands and face before breaks and immediately after handling the product.
Keep working clothes separately.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: solid
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	: Not applicable
Flash point	: Not applicable
Evaporation rate	: No data available
Flammability (solid, gas)	: No data available
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Vapour pressure	: Not applicable
Relative vapour density	: No data available
Relative density	: No data available
Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, dynamic	: No data available

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Explosive properties : No data available

Oxidizing properties : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : No decomposition if stored and applied as directed.

Possibility of hazardous reactions : No dangerous reaction known under conditions of normal use.

Conditions to avoid : Extremes of temperature and direct sunlight.

Incompatible materials : No data available

Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: 2,000 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:**Nevirapine:**

Acute oral toxicity : LD50 (Rat, female): = 502 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 1,282 mg/l
Exposure time: 4 h

Acute dermal toxicity : LD50 (Rabbit, male and female): > 2,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**Nevirapine:**

Species: Rabbit
Exposure time: 24 h
Result: No skin irritation

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Serious eye damage/eye irritation

Not classified based on available information.

Components:**Nevirapine:**

Species: Rabbit

Result: Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Components:**Nevirapine:**

Test Type: Buehler test

Species: Guinea pig

Result: Did not cause sensitisation on laboratory animals.

Germ cell mutagenicity

Not classified based on available information.

Components:**Nevirapine:**

Genotoxicity in vitro

: Test Type: Ames-test

Species: Salmonella typhimurium

Concentration: 1,7- 500 µg/plate

Result: negative

: Test Type: HGPRT assay

Species: CHO (chinese hamster ovary)

Concentration: 51-816 µg/mL

Result: negative

: Test Type: Cytogenetic assay

Species: CHO (chinese hamster ovary)

Concentration: 100 - 800 µg/plate

Result: negative

Genotoxicity in vivo

: Test Type: Micronucleus test

Species: Mouse

Dose: 2000 mg/kg

Result: negative

Carcinogenicity

Not classified based on available information.

Components:**Nevirapine:**

Remarks: Show carcinogenic effects in animal experiments.

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.

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OSHA No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

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

Not classified based on available information.

Product:

Effects on fertility :
Remarks: No data available

Effects on foetal development :
Remarks: No data available

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Nevirapine:**

Toxicity to fish : LC50 (Onchorhynchus mykiss): > 65 mg/l
Exposure time: 96 h
Test Type: static test
Method: Directive 67/548/EEC, Annex V, C.1.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 76.9 mg/l
Exposure time: 48 h
Test Type: static test
Method: Directive 67/548/EEC, Annex V, C.2.

Toxicity to algae : EC50 (Pseudokirchneriella subcapitata (microalgae)): > 43 mg/l
End point: Growth rate

EC50 (Selenastrum capricornutum (green algae)): = 5.2 mg/l
End point: Biomass

Toxicity to fish (Chronic tox- : Remarks: No data available

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icity)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available

Toxicity to bacteria : Remarks: No data available

Persistence and degradability**Product:**

Biodegradability : Result: Not readily biodegradable.
Remarks: The value is given in analogy to the following substances:

Bioaccumulative potential**Product:**

Bioaccumulation : Remarks: No data available

Components:**Nevirapine:**

Partition coefficient: n-octanol/water : log Pow: 1.81

Mobility in soil**Product:**

Distribution among environmental compartments : Remarks: No data available

Other adverse effects**Product:**

Results of PBT and vPvB assessment : Non-classified vPvB substance Non-classified PBT substance

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents.
Uncontaminated packaging can be recycled.

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SECTION 14. TRANSPORT INFORMATION**International Regulation****Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

National Regulations**SECTION 15. REGULATORY INFORMATION****EPCRA - Emergency Planning and Community Right-to-Know Act****SARA 311/312 Hazards** : No SARA Hazards**SARA 302** : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.**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.**Clean Air Act**

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

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

Pennsylvania Right To Know

Non-hazardous galenic excipients	Not Assigned	90 - 100 %
Nevirapine	129618-40-2	20 - 30 %

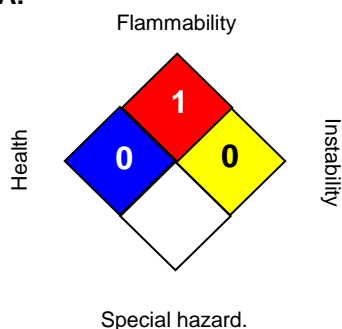
New Jersey Right To Know

Non-hazardous galenic excipients	Not Assigned	90 - 100 %
Nevirapine	129618-40-2	20 - 30 %

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California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

SECTION 16. OTHER INFORMATION**Further information****NFPA:****HMIS III:**

HEALTH	0
FLAMMABILITY	1
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

Vertical lines in the left hand margin indicate an amendment from the previous version. Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. Sources of key data used to compile the Safety Data Sheet : The specifications are based on own tests and/or literature data.

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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.