SAFETY DATA SHEET

Viramune® tablets

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

Acute toxicity (Oral): Category 4

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
SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS-No.</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nevirapine</td>
<td>129618-40-2</td>
<td>&lt; 25</td>
</tr>
</tbody>
</table>

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.
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 (NOx)
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.
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

<table>
<thead>
<tr>
<th>Components</th>
<th>Basis</th>
<th>Factor</th>
<th>Category</th>
<th>Values</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>5,6-Dihydro-11-cyclopropyl-4-methyl-6H-dipyrido[3,2-b:2',3'-e][1,4]diazepin-6-one 129618-40-2</td>
<td>ECL</td>
<td>3A</td>
<td></td>
<td>50 µg/m3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BIPC</td>
<td>1b</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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) or 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.
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

<table>
<thead>
<tr>
<th>Physical Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>solid</td>
</tr>
<tr>
<td>Colour</td>
<td>white</td>
</tr>
<tr>
<td>Odour</td>
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</tr>
<tr>
<td>Odour Threshold</td>
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</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/range</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point/boiling range</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
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</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit</td>
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</tr>
<tr>
<td>Vapour pressure</td>
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</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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
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.
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

Toxicity to daphnia and other aquatic invertebrates
EC50 (Daphnia magna (Water flea)): > 76.9 mg/l
Exposure time: 48 h
Test Type: static test

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
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 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.

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 %
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:  
- Flammability: 0
- Health: 0
- Instability: 0

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.

Revision Date: 06/03/2015

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.