



## SAFETY DATA SHEET

Norliqva (Amlodipine) Oral Solution, 1 mg/mL

SDS DATE: 12-Apr-2022

### SECTION 1: IDENTIFICATION

**PRODUCT NAME:** Norliqva (Amlodipine) Oral Solution, 1 mg/mL

**SYNONYMS:** Amlodipine Oral Solution, 1 mg/mL

**NDC Number:** 46287-035-15

**MANUFACTURER:** CMP Pharma, Inc.

**ADDRESS:** PO Box 147

8026 US Hwy. 264A

Farmville, NC 27828

**CHEMTREC PHONE:** 1-800-424-9300

**OTHER CALLS:** 1-252-753-7111

**CHEMICAL NAME (for active ingredient):** 3,5-Pyridinecarboxylic acid,2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)-1,4-dihydro-6-methyl, 3-ethyl-5-methyl ester, (+/-)-, monobenzenesulfonate

**CHEMICAL FORMULA (for active ingredient):** C<sub>20</sub>H<sub>25</sub>ClN<sub>2</sub>O<sub>5</sub>•C<sub>6</sub>H<sub>6</sub>O<sub>3</sub>S

**PHARMACOLOGICAL PROPERTIES (for active ingredient):** Calcium Channel Blocker

**PRODUCT USE:** Treatment of Hypertension and Coronary Heart Disease

### SECTION 2: HAZARD(S) IDENTIFICATION

**HEALTH HAZARDS:** Causes severe eye damage. May damage fertility of the unborn child. Toxic to aquatic life with long lasting effects.

**SIGNAL WORD:** Danger

**HAZARD SYMBOLS:**



**PRECAUTIONARY STATEMENTS:**

Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Wash hands and face thoroughly after handling. Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Immediately call a poison control center or doctor/physician.

**HAZARDS NOT OTHERWISE CLASSIFIED:** None classified.

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

<u>INGREDIENT:</u>	<u>CAS NO.</u>	<u>Amount</u>
Amlodipine Besylate	11470-99-6	0.10%
Ethanol	64-17-5	4%

\*Product also contains Maltitol, Butylated Hydroxyanisole, Frozen Peppermint Flavor, Glycerin.



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### SECTION 4: FIRST AID MEASURES

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**EYE CONTACT:** Flush with copious amounts of water for at least 15 minutes. Hold eyelids away from eyeball to ensure thorough rinsing. Irrigate each eye continuously with normal saline during transport. Seek medical attention immediately.

**SKIN CONTACT:** Wash the affected area with plenty of warm water and soap. If irritation, redness, or rash persists, seek medical attention.

**INGESTION:** Do not induce vomiting. Wash out mouth with copious amounts of water. Seek medical attention immediately.

**INHALATION:** Remove affected person to fresh air and keep patient at rest. Seek medical attention immediately.

**MOST IMPORTANT SYMPTOMS/EFFECTS**

May cause eye irritation, abdominal pain, dizziness, flushing, heart palpitations, and swelling. Antihypertensive drug; has blood pressure-lowering properties.

**NOTES TO PHYSICIANS OR FIRST AID PROVIDERS:**

None

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### SECTION 5: FIRE-FIGHTING MEASURES

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**SUITABLE EXTINGUISHING**

**MEDIA:** Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

**UNSUITABLE EXTINGUISHING**

**MEDIA:** None known.

**UNUSUAL FIRE AND EXPLOSION**

**HAZARDS:** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides, hydrogen chloride and other chlorine- and sulfur-containing compounds.

**SPECIAL FIRE FIGHTING PROCEDURES:**

Evacuate personnel to a safe area. Wear self-contained breathing apparatus and personal protective equipment to prevent contact with skin and eyes.

**PROTECTIVE MEASURES:**

Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

**MEASURES FOR ENVIRONMENTAL PROTECTIONS:**

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

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### SECTION 6: ACCIDENTAL RELEASE MEASURES

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**PERSONAL PRECAUTIONS:** Non-essential personnel should be evacuated from the affected area. Spills should be cleaned up in a manner that minimizes exposure to personnel. Personnel involved in the cleanup of spills should wear the appropriate respiratory protection, gloves, eye protection, and protective coveralls. Minimize exposure.

**METHODS/MATERIALS USED FOR CONTAINMENT & CLEANING:**

Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills. Clean spill area thoroughly.

**Environmental Precautions:**

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.



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## SECTION 7: HANDLING AND STORAGE

**HANDLING PRECAUTIONS:** Minimize dust generation and accumulation. Clean equipment and work surfaces with suitable detergent or solvent after use. Wash hands and exposed skin thoroughly with soap and water after use. Remove any contaminated clothing and clean before reuse.

**STORAGE PRECAUTIONS:** Store as directed by product packaging that is labeled in accordance with OSHA's Hazard Communication Standard [29CFR 1910.1200]. Keep this drug out of the reach of children.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### EXPOSURE LIMITS/GUIDELINES:

Component Name	WEEL (TWA)	OSHA PEL (TWA)	ACGIH TLV (TWA)	HSE WEL (TWA)
Amlodipine Besylate	N/A	100 µg/m <sup>3</sup>	N/A	N/A

**ENGINEERING CONTROLS:** In a manufacturing setting, local exhaust ventilation may be necessary to control air contaminants. The use of local ventilation is recommended to control emissions near the source. Provide mechanical ventilation for confined spaces. If user operations generate aerosols, use ventilation to keep exposure to airborne contaminants below the exposure limit.

### PERSONAL PROTECTIVE EQUIPMENT (PPE)

**EYE PROTECTION:** Wear appropriate chemical safety goggles, safety glasses, or face shield as described by OSHA's eye and face protection regulations in 29 CFR 1910.133. Have eyewash stations available where eye contact can occur.

**SKIN PROTECTION:** Avoid unintended skin contact. Wear gloves impervious to conditions of use. Additional protection may be necessary to prevent skin contact including the use of an apron, face shield, boots, or full body protection. A safety shower should be located in the work area.

**RESPIRATORY PROTECTION:** If exposure limits are exceeded, approved respiratory protection should be worn. Seek professional assistance for proper selection of respiratory protection.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

**APPEARANCE/ODOR:** This product is a clear, straw colored, viscous liquid with a frozen peppermint odor.  
**ODOR THRESHOLD:** No data available.

<b>FLASH POINT:</b>	Not established.	<b>% VOLATILE:</b>	Not established.
<b>AUTOIGNITION TEMP:</b>	Not established.	<b>VISCOSITY:</b>	Not established.
<b>BOILING POINT:</b>	Not established.	<b>UPPER FLAMMABILITY LIMIT:</b>	Not established.
<b>MELTING POINT:</b>	Not established.	<b>Octanol/H<sub>2</sub>O PART. COEFFICIENT:</b>	Not established.
<b>VAPOR PRESSURE (mmHg):</b>	Not established.	<b>POUR POINT:</b>	Not established.
<b>EVAPORATION RATE (H<sub>2</sub>O = 1):</b>	Not established.	<b>% SOLUBILITY IN WATER:</b>	Not established.
<b>VAPOR DENSITY (AIR = 1):</b>	Not established.		
<b>LOWER FLAMMABILITY LIMIT:</b>	Not established.		

## SECTION 10: STABILITY AND REACTIVITY



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**REACTIVITY:** No available data.

**POSSIBILITY OF HAZARDOUS REACTIONS:** Material is stable under normal conditions and storage.

**CONDITIONS TO AVOID:** Fine particles (such as dust and mist) may fuel fires/explosions.

**INCOMPATIBLE MATERIALS:** Strong oxidizing agents.

**HAZARDOUS DECOMPOSITION PRODUCTS:** No data available.

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### SECTION 11: TOXICOLOGICAL INFORMATION

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#### INFORMATION ON LIKELY ROUTES OF EXPOSURE:

**INGESTION:** May be harmful if swallowed. May cause eye irritation (based on components). Antihypertensive drug; has blood pressure-lowering properties.

**INHALATION:** No data available.

**SKIN CONTACT:** No data available.

**EYE CONTACT:** Avoid contact with eyes. May cause irritation of the eyes.

#### SIGNS AND SYMPTOMS OF OVEREXPOSURE:

Eye irritation, abdominal pain, dizziness, flushing, heart palpitations, and swelling.

**ACUTE TOXICITY VALUES:** LD 50 for active ingredient (oral, rat) = 393 mg/kg

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### SECTION 12: ECOLOGICAL INFORMATION

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#### ECOLOGICAL INFORMATION:

This product has not been tested for persistence, biodegradability, bioconcentration, soil absorption, or mobility. Care should be taken to avoid environmental release.

#### ECOTOXICITY INFORMATION:

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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### SECTION 13: DISPOSAL CONSIDERATIONS

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#### WASTE DISPOSAL METHOD:

It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Waste disposal must be in accordance with all local, state, and federal regulations. Wear proper protective equipment when handling waste materials.

#### WASTE DISPOSAL CONTAINERS:

Waste materials must be placed in and shipped in appropriate poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers is done in accordance with all applicable regulations.

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### SECTION 14: TRANSPORT INFORMATION

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#### U.S. DEPARTMENT OF TRANSPORTATION SHIPPING REGULATIONS:

This product is not regulated.



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## SECTION 15: REGULATORY INFORMATION

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### U.S. FEDERAL REGULATIONS

#### TOXIC SUBSTANCE CONTROL ACT (TSCA):

All components of this product are included on the TSCA inventory.

#### CLEAN WATER ACT (CWA):

There are no ingredients in this mixture listed in the Clean Water Act.

#### CLEAN AIR ACT (CAA):

There are no ingredients in this mixture listed under the Clean Air Act.

#### SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT):

There are no ingredients in this mixture listed under SARA.

#### STATE REGULATIONS:

Complies with OSHA standards. 29CFR1910.

### INTERNATIONAL REGULATIONS:

#### CANADIAN ENVIRONMENTAL PROTECTION ACT:

Listed

#### CANADIAN WORKPLACE HAZARDOUS MATERIALS INFORMATION SYSTEMS (WHMIS):

Listed

#### EUROPEAN INVENTORY OF EXISTING CHEMICALS (EINECS):

Listed

#### EU CLASSIFICATION:

European labeling in accordance with EC directives.

#### EU RISK (R) AND SAFETY (S) PHRASES (OCCUPATIONAL EXPOSURE):

R38 Irritating to skin  
R43 May cause sensitization by skin contact  
R61 May cause harm to unborn child  
S2 Keep out of the reach of children  
S36/27 Wear suitable protective clothing and gloves

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## SECTION 16: OTHER INFORMATION

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CREATION DATE: 12Apr2022

REVISION DATE: 12Apr2022

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