

SAFETY DATA SHEET

Guanfacine Tablets, USP 1 mg and 2 mg

Section 1. Identification of the substance

Identification of the product

Product name	: Guanfacine Tablets, USP
Potencies	: 1 mg and 2 mg
Chemical Name	: N-amidino-2-(2,6-dichlorophenyl) acetamide monohydrochloride.
Therapeutic Category	: Antihypertensive
Product Use	: Management of hypertension.
Marketed by	: Ajanta Pharma USA Inc. Bridgewater, NJ 08807. Made in India
Contact Information	: 855-664-7744

Section 2. Composition / information on ingredients

Active ingredient: Guanfacine Hydrochloride

Inactive ingredients: Anhydrous citric acid, microcrystalline cellulose, pregelatinized starch, stearic acid.

Section 3. Health hazards information

Pharmaceutical Agent	: Handling of this product in its final form presents minimal occupational exposure risk. .
Classification	: Not classified
Label elements	: Not classified
Other Hazards	: No information available

Unknown acute toxicity : No information available

Section 4. First aid measures

This is a pharmaceutical product in its final dosage form (tablets). The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

Description of first aid measures

- Overdose** : Refer to information on package labeling and packaging. In case of overdose, get medical help or contact a Poison Control Center right away.
- General advice** : Never give anything by mouth to an unconscious person. IF exposed or concerned: Get medical advice/attention. Show this safety data sheet to the doctor in attendance.
- Inhalation** : IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention immediately if symptoms occur.
- Skin contact** : Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention.
- Eye contact** : In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
- Ingestion** : Do not induce vomiting without medical advice. Rinse mouth thoroughly with water. Get medical attention if symptoms occur.
- Self-protection of the first aider** : First aider: Pay attention to self-protection. Do not breathe dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.
- Symptoms** : Dry mouth, dizziness, somnolence, fatigue, headache and nausea.
- Indication of any immediate medical attention and special treatment needed** : Treat symptomatically. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Section 5. Fire-fighting measures

Flash Point	: Not Applicable.
Suitable Extinguishing Media	: Use extinguishing measures such as water spray, alcohol-resistant foam, carbon dioxide, dry chemical powder or appropriate foam, that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	: None known.
Fire hazard	: Not flammable.
Explosive hazard	: Not an explosive.
Reactivity	: Hazardous reactions will not occur under normal conditions.
Hazardous combustion products	: Carbon oxides, Nitrogen oxides, Hydrogen chloride.

Section 6. Accidental release measures

This is a pharmaceutical product in its final dosage form (tablets). The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

Personal Precautions	: Avoid contact with skin, eyes or clothing. Do not breathe dust/fume/gas/mist/vapors/spray. Use personal protective equipment as required.
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For non-emergency personnel

Personal Protective Equipment	: Use personal protective equipment as required.
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Emergency procedures	: Evacuate personnel to safe areas.
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For emergency responders

Personal Protective Equipment	: Use personal protective equipment as required.
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Emergency procedures	: Evacuate personnel to safe areas. Ventilate the area. Eliminate all ignition sources if safe to do so.
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Environmental Protections	: Do not flush into surface water or sanitary sewer system. Should not be released into the environment.
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Methods for containment	: Prevent further leakage or spillage if safe to do so.
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- Methods for cleaning up** : Use appropriate personal protective equipment (PPE). Carefully shovel or sweep up spilled material and place in suitable container. Avoid generating dust. For spills: Soak with inert absorbent material. Use clean non-sparking tools to collect absorbed material. Avoid breathing dust or spray mist.

Section 7. Handling and storage

- Patients/Consumers** : Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.
- Storage Conditions** : Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) see USP Controlled Room Temperature].

Section 8. Exposure controls/personal protection

This is a pharmaceutical product in its final dosage form (tablets). The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

- Exposure Limits** : No information available.
- Appropriate engineering controls** : Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.
- Hand protection** : Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.
- Eye/face protection** : Safety glasses with side shields are recommended for medical or industrial exposures.
- Skin and body protection** : Wear suitable protective clothing.
- Respiratory protection** : No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required. If exposure limits are exceeded or irritation is

experienced, NIOSH/MSHA approved respiratory protection should be worn.

Section 9. Physical and chemical properties
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Physical state	: Solid
Appearance	: 1 mg: White to off white, round, biconvex tablets, debossed with 'G1' on one side and plain on other side. Bottles of 100 with child-resistant closure NDC 27241-242-01. 2 mg: White to off white, oval, biconvex tablets, debossed with 'G2' on one side and plain on other side. Bottles of 100 with child-resistant closure NDC 27241-243-01.
Odor threshold	: No data available
pH	: No data available
Melting point / freezing point:	: No data available
Boiling point / boiling range	: No data available
Flash point	: No data available
Evaporation rate	: No data available
Flammability (solid, gas)	: No data available
Upper flammability limit	: No data available
Lower flammability limit	: No data available
Vapor pressure	: No data available
Vapor density	: No data available
Relative density	: No data available
Water solubility	: No data available
Solubility in other solvents	: No data available
Partition coefficient	: No data available

Autoignition temperature	: No data available
Decomposition temperature	: No data available
Kinematic viscosity	: No data available
Dynamic viscosity	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
VOC Content(%)	: No data available

Section 10. Stability and reactivity

Reactivity	: Hazardous reactions will not occur under normal conditions.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: None under normal processing.
Conditions to avoid	: Extremes of temperature, High humidity (above 60%) and direct sunlight.
Incompatible materials	: Strong oxidizing agents, strong acids, and strong bases.
Hazardous decomposition	: Decomposition will not occur under normal conditions products.

Section 11. Toxicological information

Inhalation	: Not an expected route of exposure.
Ingestion	: May be harmful if swallowed in amounts above the therapeutic dose.
Eye contact	: Not an expected route of exposure.
Skin contact	: Not an expected route of exposure.
Symptoms	: Somnolence, Fatigue, and Dizziness. May decrease blood pressure and cause other cardiac effects.

Skin corrosion/irritation	: Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	: Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	: Not applicable.
Germ cell mutagenicity	: Based on available data, the classification criteria are not met.
Carcinogenicity	: Based on available data, the classification criteria are not met.
Reproductive toxicity	: Based on available data, the classification criteria are not met.
STOT - single exposure	: Based on available data, the classification criteria are not met.
STOT - repeated exposure	: Based on available data, the classification criteria are not met.
Acute toxicity	: No information available

Section 12. Ecological information

Ecotoxicity	: No information available.
Persistence and degradability	: No information available.
Bioaccumulation	: No information available.
Mobility	: No information available.
Other adverse effects	: No information available.

Section 13. Disposal consideration

Waste treatment methods: Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable. Dispose of waste in accordance with environmental legislation. Do not flush into surface water or sanitary sewer system.

Section 14. Transport information

Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.

Transport hazard class(es): Not Regulated

Packing group : Not regulated

Environmental hazards : No

Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable

Section 15. Regulatory information

DEA: It is not a DEA regulated scheduled drug.

FDA: Guanfacine Tablets, USP is an approved prescription medication.

Inventory Status: This material is not listed on the US TSCA Inventory.

Section 16. Disclaimer

This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warning included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace. The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing here in shall be deemed to create any warranty, express or implied.

Ajanta shall not be held liable for any damage resulting from handling or from contact with the above product.

Date: May 03, 2023

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION