SAFETY DATA SHEET

Captopril Tablets, USP 12.5 mg, 25 mg, 50 mg and 100 mg

EMERGENCY OVERVIEW

Captopril Tablets, USP contain an active drug substance Captopril USP and pharmaceutical excipients generally considered safe, non-toxic and non-hazardous. The quantities of the excipients used in the product are well within the IID (Inactive Ingredient Database) limits prescribed by USFDA for oral route.

WARNING: Accidental ingestion of large amounts may be harmful.

Section 1. Identification of the substance

Identification of the product

Product name	**:**	Captopril Tablets, USP
Potencies	**:**	12.5 mg, 25 mg, 50 mg and 100 mg
Chemical Name	**:**	1-[(2S)-3-mercapto-2-methylpropionyl]-L-proline
Therapeutic Category	**:**	Angiotensin-I converting enzyme (ACE) inhibitor
Product Use	**:**	Treatment of hypertension, congestive heart failure, diabetic nephropathy (proteinuria > 500 mg/day) in patients with type-I insulin-dependent diabetes mellitus and retinopathy. It is also indicated in indicated to improve survival following myocardial infarction in clinically stable patients with left ventricular dysfunction
Marketed by	**:**	**Ajanta Pharma USA Inc**. Bridgewater, NJ 08807. Made in India
Contact Information	**:**	855-664-7744

Section 2. Health hazards information

Potential Health Effects	**:**	**Inhalation:** Not expected to be hazardous in final pharmaceutical form. **Eye Contact**: Not expected to be hazardous in final pharmaceutical form. **Skin Contact:** May cause an allergic skin reaction.

Ingestion: Health injuries are not known or expected under normal use. Exposures above clinical dosage could result in adverse effects. Minor occupational exposures are not expected to be harmful.
Fertility: May damage fertility or the unborn child.

Effects of Overexposure : The potential for exposure is reduced in finished pharmaceutical dosage form.

Section 3. Composition / information on ingredients

Active ingredient	Exposure Limit	CAS No.
Captopril USP	--	62571-86-2

Inactive ingredients: The inactive ingredients include microcrystalline cellulose, lactose, crospovidone, colloidal silicon dioxide and stearic acid.

Section 4. First aid measures

The product in the final dosage form (tablet) does not pose a problem of exposure to active drug substance and should not cause inhalation, skin and eye irritation problem. However, in case of exposure:

Eye Contact : Immediately flush eyes with water, occasionally lifting the upper and lower eyelids for at least 20 minutes. Check for and remove any contact lenses. Get medical attention.

Skin Contact : Immediately wash skin with plenty of soap and water for at least 20 minutes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Get medical attention if symptoms occur. Wash clothing and shoes thoroughly before reuse.

Ingestion : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed by a conscious person, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. DO NOT induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately.

Inhalation : Remove to fresh air and keep patient at rest in a position comfortable for breathing. If not breathing, give artificial respiration or oxygen by trained personnel. Get immediate medical attention immediately. If unconscious, place in recovery position and get medical attention immediately.

Medical Treatment	:	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.

Section 5. Fire-fighting measures

Flash Point	:	Not available.
Extinguishing Media	:	Extinguish fire with extinguishing agent suitable for the surrounding fire
General Fire Hazards/ Hazardous Combustible Products	:	Decomposition products may include carbon dioxide, carbon monoxide, nitrogen oxides, sulfur oxides and metal oxides
Special Fire Fighting Procedures	:	Wear self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode and full protective gear to prevent contact with skin and eyes.

Section 6. Accidental release measures

Personal Precautions	:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Environmental Protections	:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).
Clean-up Methods	:	Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor.
Additional Consideration for Large Spills	:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Move containers from spill area. Clean up operations should only be undertaken by trained personnel.

Section 7. Handling and storage

Handling : Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Avoid exposure - obtain special instructions before use. Avoid exposure during pregnancy. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. If during normal use the material presents a respiratory hazard, use only with adequate ventilation or wear appropriate respirator. Empty containers retain product residue as they can be hazardous. Do not reuse container.

Storage : Recommended storage for Captopril tablets, USP: 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]. Keep bottles tightly closed (protect from moisture).

Section 8. Exposure controls/personal protection

Exposure Limits : None

Engineering Controls : In laboratory, medical or industrial setting use appropriate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

Respiratory Protection : For consumer use, no unusual precaution are necessary. However, for handling in laboratory, medical or industrial setting use approved respirators for protection if necessary. Use a properly fitted, particulate filter respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Personal Protection : For consumer use, no unusual precaution are necessary. However, for handling in laboratory, medical or industrial setting use gloves as recommended. Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Recommended Facilities : None

Section 9. Physical and chemical properties

Appearance : Captopril tablets, USP are available containing 12.5 mg, 25 mg, 50 mg or 100 mg of captopril, USP.

The 12.5 mg tablets are white to off-white, oval shaped, flat beveled edged uncoated tablets having break line on both sides and one side debossed with "C" on one side of the break line and "1" on other side of the break line (bisect). They are available as follows:
NDC 27241-160-01 bottles of 100 tablets with child-resistant closure
NDC 27241-160-10 bottles of 1000 tablets

The 25 mg tablets are white to off-white, round, flat beveled edged, uncoated tablets debossed with "2" over "C" one side and quadrisect score on the other side. They are available as follows:
NDC 27241-161-01 bottles of 100 tablets with child-resistant closure
NDC 27241-161-10 bottles of 1000 tablets

The 50 mg tablets are white to off-white, round, flat beveled edged, uncoated tablets debossed with "3" above the break line and "C" below the break line one side (bisect) and plain on the other side. They are available as follows:
NDC 27241-162-01 bottles of 100 tablets with child-resistant closure
NDC 27241-162-10 bottles of 1000 tablets

The 100 mg tablets are white to off-white, round, flat beveled edged, uncoated tablets debossed with "4" above the break line and "C" below the break line on one side (bisect) and plain on the other side. They are available as follows:
NDC 27241-163-01 bottles of 100 tablets with child-resistant closure

Bottles contain a desiccant-charcoal canister.

All captopril tablets, USP are white to off-white and may exhibit a slight sulfurous odor.

Other Information : Captopril USP (Molecular weight: 217.28) is a white to off-white crystalline powder that may have a slight sulfurous odor; it is soluble in water (approx. 126 mg/mL), methanol, and ethanol and sparingly soluble in chloroform and ethyl acetate.

Section 10. Stability and reactivity

Stability	:	Stable
Incompatibility	:	Incompatible with strong oxidizing agent and alkalis.
Hazardous Decomposition	:	Under normal conditions of storage and use, hazardous decomposition products should not be produced.
Conditions to Avoid	:	Incompatible materials, strong oxidants and alkalis.

Section 11. Toxicological information

Acute toxicity	:	Rat Oral LD50: 4245 mg/kg
Carcinogenesis	:	None of the components of this product are suspected to be a carcinogen.
Mutagenesis	:	When processed and used as directed, this product is not expected to produce mutagenic effects in humans.
Fertility effects	:	May damage fertility.
Teratogenicity	:	May damage the unborn child.

Section 12. Ecological information

Eco toxicity of drug substance	:	The active ingredient in this formulation is water soluble and expected to remain in water and migrate through the soil into the groundwater.
In the finished product form	:	There is no potential for air borne contamination since the drug substance is in consolidated form as tablets.

Section 13. Disposal consideration

Waste Disposal Considerations: Dispose the material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

This product is not subject to the regulations for the safe transport of hazardous chemicals

DOT: Not regulated for transport of dangerous goods.
IATA: Not regulated for transport of dangerous goods
IMDG: Not regulated for transport of dangerous goods

Section 15. Regulatory information

DEA: Not Available.
FDA: Captopril tablets, USP 12.5 mg, 25 mg, 50 mg and 100 mg is an approved prescription medication.

Section 16. Disclaimer

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 herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

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

Date: Mar 31, 2022

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION