

SAFETY DATA SHEET

Primidone Tablets USP, 50 mg and 250 mg

Version: 01

Issue Date: 02/07/2024

1. IDENTIFICATION:

Product Name: Primidone Tablets USP, 50 mg and 250 mg

Recommended Use: Rx. Pharmaceutical. Use only as directed.

Uses Advised Against: Control of grand mal, psychomotor, and focal epileptic seizures

Manufacturer and Distributor:

Carnegie Pharmaceuticals LLC

600, Delran pkwy,

Delran, New Jersey, 08075

USA

Emergency: (732) 783-7011 or call 911

Information: (732) 783-7011

2. HAZARDS IDENTIFICATION:

Hazard Classification: Pharmaceutical Agent- Handling of this product in its final form presents minimal occupational exposure risk.

Emergency overview: None

Potential Health Effects: Eyes

None

Potential Health Effects: Skin

None

Potential Health Effects: Ingestion.

Possible allergic reaction if ingested, evidence be drowsiness, giddiness, and nausea.

Potential Health Effects: Inhalation.

None

Other Hazards: Other Hazards.

None

3. COMPOSITION / INFORMATION ON INGREDIENT:

Ingredient	CAS number
Primidone, USP	125-33-7
Lactose Monohydrate, NF	64044-51-5
Sodium Lauryl Sulfate, NF	151-21-3
Methyl Cellulose, USP	9004-67-5
Microcrystalline Cellulose, NF	9004-34-6
Sodium Starch Glycolate, NF	9063-38-1
Magnesium Stearate, NF	557-04-0
Talc, USP	14807-96-6

4. FIRST AID MEASURES:

Description of Most important symptoms and effects, both acute and delayed, and first-aid measures.

General Symptoms/Injuries: Refer to package insert for more detailed general information.

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice.

Symptoms/Injuries after Inhalation: None

First-Aid Measures After Inhalation: None

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Symptoms/Injuries after Skin Contact: None

First-aid Measures after Skin contact: None

Symptoms/Injuries after Eye Contact: None

First-Aid Measures after Eye Contact: None

Symptoms/Injuries After Ingestion: Possible allergic reaction if ingested, evidence be drowsiness, giddiness, and nausea.

First-aid Measures After Ingestion: Drink plenty of water. Seek medical attention.

Chronic Symptoms: None expected under normal conditions of use.

5. FIRE FIGHTING MEASURES:

Extinguishing Media: Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: N/A

Special Hazards Arising from the substance or Mixture.

May emit toxic fumes.

Hazardous Combustion Products: Not determined.

Advice for Firefighters: None

Firefighting Instructions: Exercise caution when fighting any chemical fire.

Protection during Firefighting: Firefighters should wear full protective gear.

6. ACCIDENTAL RELEASE MEASURES:

Personal Precautions, Protective Equipment and Emergency Procedures.

General Measures: Avoid all eye and skin contact and do not breathe vapor and mist.

For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Isolate area. Evacuate unnecessary personnel.

For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.

Methods and Material for Containment and Cleaning up.

Containment Procedures: Stop the flow of material if this is without risk.

Methods for Cleaning up: Wipe up spills and rinse area with water. Dispose of these materials in accordance with federal, state, and local regulations.

7. HANDLING AND STORAGE:

Precautions for Safe handling: Store in tight container. Use according to label directions.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

Storage conditions: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Dispense in a tight, light-resistant container with a child-resistant closure.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION:

Appropriate Engineering Controls: None

Personal Protective Equipment

Hand protection: None

Eye Protection: None

Skin and Body Protection: None

Respiratory Protection: None

Other information: None

9. PHYSICAL AND CHEMICAL PROPERTIES:

Product Strength: Primidone Tablets USP, 50 mg and 250 mg

Physical State: Solid

NDC:

Strength	Counts	NDC
50 mg	100	80005-117-11
	500	80005-117-14
	1000	80005-117-15
250 mg	100	80005-118-11
	500	80005-118-14
	1000	80005-118-15

Package:

Product Strength	Counts	Packaging Material	
50 mg	100	Bottle	40 cc HDPE white bottles 33/400
		Cap	33mm/400 CRC with a heat induction foil liner HS035.020
		Rayon	12 grams
	500	Bottle	75 cc HDPE White Bottles 38/400
		Cap	38mm/400 CRC with a Heat induction foil liner HS035.020
		Rayon	12 grams
	1000	Bottle	150 cc HDPE White Bottles 45/400
		Cap	38mm/400 CRC with a Heat induction foil liner HS035.020
		Rayon	12 grams
250 mg	100	Bottle	75 cc HDPE White Bottles 38/400
		Cap	38mm/400 CRC with a Heat induction foil liner HS035.020
		Rayon	12 grams
	500	Bottle	300 cc HDPE White Bottles 45/400
		Cap	45mm/400 CT with a Heat induction foil liner HS035.020
		Rayon	12 grams
	1000	Bottle	625 cc HDPE White Bottles 53/400
		Cap	53mm/400 CT with a Heat induction foil liner HS035.020
		Rayon	12 grams

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10. STABILITY AND REACTIVITY:

Reactivity: Hazardous reactions will not occur under normal conditions.

Chemical Stability: This is a stable material.

Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

Conditions to Avoid: Not determined.

Incompatible Materials: Not determined.

Hazardous Decomposition Products: None.

11. TOXICOLOGICAL INFORMATION:

Acute Dose Effects:

General Product information: No information available for the product.

Carcinogenicity:

General Product Information: No information available for the product.

12. ECOLOGICAL INFORMATION:

Avoid release to the environment.

13. DISPOSAL CONSIDERATIONS:

Waste treatment methods:

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

Ecology- Waste Materials: Avoid release to the environment.

14. TRANSPORT INFORMATION:

Not regulated for transport.

15. REGULATORY INFORMATION:

Prescription Drug status: Rx only

US Federal Regulations: None.

US State Regulations:

The following components appear on one of the following state hazardous substance lists: None.

16. OTHER INFORMATION:

No other information is available.

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