

## SAFETY DATA SHEET (SDS)

Telmisartan Tablets USP, 20 mg, 40 mg, 80 mg

Revision Date: 17-January-2023

Version 1.0

### 1. IDENTIFICATION

**Product Name:** Telmisartan Tablets USP, 20 mg, 40 mg, 80 mg

**Product Information:** Telmisartan Tablets

**Company Name:** Cadila Pharmaceuticals Limited

**Address:** 1389, Dholka – 382225, District: Ahmedabad, Gujarat State, India.

**Phone No.:** 02714/221481

**Fax No.:** 02714/220315

### 2. HAZARD(S) IDENTIFICATION:

**Physical hazards** Not classified.

**Health hazards** Not classified.

**OSHA defined hazards** Not classified.

#### Label elements

Hazard symbol None.

Signal word None.

Hazard statement This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.

#### Precautionary statement

Prevention Observe good industrial hygiene practices.

Response Wash hands after handling.

Storage Store at 25°C (77°F); excursions permitted to 15 - 30 °C (59 - 86 °F).

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations. Incineration of waste at an approved USEPA incinerator is recommended.

#### Hazard(s) not otherwise

classified (HNOC) None known.

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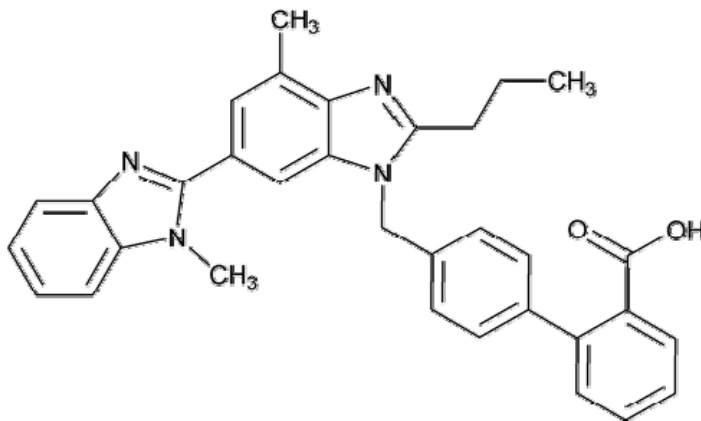
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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

**Chemical Name:** 4'-[[[4-methyl-6-(1-methyl-2-benzimidazolyl)-2-propyl-1-benzimidazolyl]methyl]-2-biphenyl carboxylic acid



Telmisartan, USP

**Product Code:** Not applicable

**Hazardous Ingredients / Components:** Not Applicable

**CAS No.:** 144701-48-4

**Other Components:**

Inactive Ingredients	Exposure Limit	CAS No.
Sodium hydroxide	Not Found	1310-73-2
Meglumine	Not Found	6284-40-8
Povidone	Not Found	25655-41-8
Mannitol	Not Found	69-65-8
Magnesium stearate	Not Found	557-04-0

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### 4. FIRST – AID MEASURES

**Inhalation:** If dust from the material is inhaled, remove the affected person immediately to fresh air. Call a physician if symptoms develop or persist.

**Skin Contact:** Wash off with soap and water. Get medical attention if irritation develops and persists.

**Eye Contact:** Rinse with water. Get medical attention if irritation develops and persists.

**Ingestion:** Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.

**Most important symptoms/effects, acute and delayed:** Most common side effects are dizziness, fatigue, and musculoskeletal pain. Persistent dry cough has been associated with ACE-inhibitor use.

**Indication of immediate medical attention and special treatment needed:** Provide general supportive measures and treat symptomatically.

**General information:** Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

### 5. FIRE-FIGHTING MEASURES

**Suitable Extinguishing Media:** Water fog. Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>).

**Unsuitable extinguishing media:** Do not use water jet as an extinguisher, as this will spread the fire.

**Specific hazards arising from the Chemical:** During fire, gases hazardous to health may be formed.

**Special protective equipment and precautions for firefighters:** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

**Fire fighting equipment/instructions:** Use water spray to cool unopened containers.

**Specific methods:** Use standard firefighting procedures and consider the hazards of other involved materials.

**General fire hazards:** No unusual fire or explosion hazards noted.

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### 6. ACCIDENTAL RELEASE MEASURES

**Protective precautions, Protective Equipment and Emergency Procedures:** Keep unnecessary personnel away. Wear appropriate personal protective equipment (see Section 8).

**Methods and Material for Containment and Cleaning Up:** Sweep up and place into a proper container for disposal. Minimize dust generation and accumulation. Collect dust using a vacuum cleaner equipped with HEPA filter. Following product recovery, flush area with water. Incineration of waste at an approved USEPA incinerator is recommended.

**Environmental precautions:** Avoid discharge into drains, water courses or onto the ground.

### 7. HANDLING AND STORAGE

**Precautions for safe handling:** Avoid contact with eyes, skin, and clothing. Avoid breathing dust. Wash hands thoroughly after handling.

**Storage:** Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F) [see USP Controlled Room Temperature].

### 8. EXPOSURE CONTROL / PERSONAL PROTECTION

**Engineering Controls:** Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

**Personal protection equipment:**

- **Eye Protection:** Safety glasses
- **Protective Gloves:** Compatible chemical-resistant gloves
- **Other Protective Clothing:** Lab coat

**Respiratory Equipment (Specify Type):** NIOSH approved respirator, as conditions warrant.

- **Work/ Hygienic:** Do not take internally. Facilities storing or utilizing this material should be equipped with an eyewash and a safety shower. Wash thoroughly after handling.

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#### 9. PHYSICAL AND CHEMICAL PROPERTIES

##### Appearance:

##### Telmisartan Tablets 20 mg

White to off-white, round shaped, uncoated tablet, debossed with “C44” on one side and plain on other side.

##### Telmisartan Tablets 40 mg

White to off-white, oblong, biconvex, uncoated tablet, debossed with “C141” on one side and plain on other side.

##### Telmisartan Tablets 80 mg

White to off-white, oval, biconvex, uncoated tablet, debossed with “C144” on one side and plain on other side.

**Odour** No Data Available

**pH** Not Applicable

**Melting Point** No Data Available

**Boiling Point** No Data Available

**Flash Point** No Data Available

**Evaporation Rate** No Data Available

**Flammability (solid, gas)** No Data Available

**Explosive Limits** Not Applicable

**Vapor Density** Not Available.

**Specific Gravity** No Data Available

**Solubility in Water** Not Available.

**Partition coefficient  
(n-octanol/Water)** Not Available

**Autoignition Point** Not Available

**Decomposition Temperature** Not Applicable

**Viscosity** Not Applicable

**Molecular formula:** C<sub>33</sub>H<sub>30</sub>N<sub>4</sub>O<sub>2</sub>

**Molecular weight:** 514.6 g/mol

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### 10. STABILITY AND REACTIVITY

**Reactivity:** The product is stable and non-reactive under normal conditions of use, storage and transport.

**Chemical stability:** Material is stable under normal conditions.

**Possibility of hazardous reactions:** No dangerous reaction known under conditions of normal use.

**Conditions to avoid:** Contact with incompatible materials. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).

**Incompatibility Materials:** Strong oxidizing agents.

**Hazardous Decomposition Product(s):** Carbon oxides.

### 11. TOXICOLOGY INFORMATION

**Toxicological Effects:** Telmisartan - Toxicity Data: Oral TDLO (man): 32 mg/kg; Intraperitoneal TDLO (mouse): 3 mg/kg; Oral TDLO (rat): 2 mg/kg;

**Chronic Toxicological:** Telmisartan - Investigated as a mutagen. Only select Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information. Telmisartan RTECS Number: DV2037500

### 12. ECOLOGICAL INFORMATION

**Toxicity:** Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.

**Persistence and Degradability:** No data available.

**Bioaccumulative Potential:** No data available.

**Mobility in Soil:** No data available.

**Results of PBT and vPvB assessment:** No data available.

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### 13. DISPOSAL CONSIDERATIONS

Dispose in accordance with local, state, and federal regulations.

### 14. TRANSPORT INFORMATION

<b>DOT</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not available

### 15. REGULATORY INFORMATION

Generic Medicine. Approved by USFDA on July 25, 2017 and the ANDA Number is 208605.

### 16. OTHER INFORMATION

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance, patients should consult prescribing information/ package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.