Safety Data Sheet
Telmisartan Tablets, USP

Strength: 20/40/80mg. **Pack Size:** 30/90/100/500/1000 Tablets per bottle **Revision No.:** 03
Cartons of 30 tablets (3 x 10 unit-dose)

EMERGENCY OVERVIEW

Each Telmisartan Tablets contain Telmisartan and excipients generally considered to be non -toxic and non - hazardous in small quantities and under conditions of normal occupational exposure.

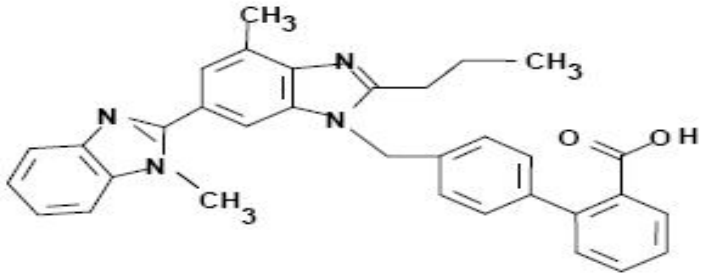
Section 1. Identification

Identification of the product

Product name: Telmisartan Tablets USP

Formula: $C_{33}H_{30}N_4O_2$

Chemical Name: 4'-[(1,4'-dimethyl-2'-propyl [2,6'-bi-1H-benzimidazol]-1'-yl)methyl]-[1,1'-biphenyl]-2-carboxylic acid.



Telmisartan, USP

Manufacturer / supplier identification

Company: **Cadila Healthcare Ltd. Ahmedabad, India**

Address: Sarkhej – Bavla. N.H. 8A, Moraiya. Tal. Sanand.
Dist. Ahmedabad – 382210. State: Gujarat. India

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Recommended use / Therapeutic Category Non-peptide angiotensin II receptor (type AT_1) antagonist.

Restriction on Use / Contraindications: Known hypersensitivity (e.g., anaphylaxis or angioedema) to telmisartan or any other component of this product.
Do not coadminister aliskiren with telmisartan in patients with diabetes.

Section 2. Hazard(s) Information

Dose and Administration

Dosage must be individualized. The usual starting dose of telmisartan tablets is 40 mg once a day. Blood pressure response is dose-related over the range of 20 to 80 mg.

Most of the antihypertensive effect is apparent within 2 weeks and maximal reduction is generally attained after 4 weeks. When additional blood pressure reduction beyond that achieved with 80 mg telmisartan is required, a diuretic may be added.

No initial dosage adjustment is necessary for elderly patients or patients with renal impairment, including those on hemodialysis. Patients on dialysis may develop orthostatic hypotension; their blood pressure should be closely monitored.

Telmisartan Tablets may be administered with other antihypertensive agents.

Telmisartan Tablets may be administered with or without food.

Adverse Effects

The most common adverse events (≥ 1%) reported in hypertension trials are back pain, sinusitis, and diarrhea.

Over Dose Effect

The most likely manifestation of overdosage with telmisartan tablets would be hypotension, dizziness and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation.

Medical Conditions

Before you take Telmisartan tablets, tell your doctor if you:

- have liver problems
- have kidney problems
- have heart problems
- have any other medical conditions
- are pregnant or are planning to become pregnant.
- are breast-feeding or plan to breast-feed. It is not known if telmisartan passes into your breast milk. You and your doctor should decide if you will take telmisartan tablets or breastfeed. You should not do both. Talk with your doctor about the best way to feed your baby if you take telmisartan tablets.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

For patients with diabetes, if you are taking telmisartan you should not take aliskiren.

Telmisartan may affect the way other medicines work, and other medicines may affect how telmisartan works. Especially tell your doctor if you take:

- aliskiren
- digoxin (Lanoxin®, Lanoxicaps®)
- lithium (Eskalith®, Lithobid®)
- medicines used to treat pain and arthritis, called non-steroidal anti-inflammatory drugs (NSAIDs), including COX-2 inhibitors
- ramipril (Altace®) or other medicines used to treat your high blood pressure or heart problem
- water pills (diuretic)

Know the medicines you take. Keep a list of them and show it to your doctor or pharmacist when you get a new medicine.

Contraindications Known hypersensitivity (e.g., anaphylaxis or angioedema) to telmisartan or any other component of this product
Do not coadminister aliskiren with telmisartan in patients with diabetes

Pregnancy Comments When pregnancy is detected, discontinue telmisartan as soon as possible

Pregnancy Category D

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component:		
Telmisartan	Not Found	144701-48-4
Inactive ingredients :		
Ferric oxide red	Not Found	1903-37-1
Lactose monohydrate	Not Found	5989-81-1
Magnesium stearate	Not Found	557-04-0
Meglumine	Not Found	6284-40-8
Povidone	Not Found	9003-39-8
Sodium hydroxide	Not Found	1310-73-2
Sodium stearyl fumarate	Not Found	4070-80-8
Sorbitol	Not Found	50-70-4

Section 4. First -aid measures

General

Inhalation: Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

Contact with skin: Immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.

Contact with eyes: Immediately flush eyes with copious amounts of water for at least 15 minutes. Seek medical advice

Ingestion: If swallowed, wash out mouth with water, provided person is concious. Seek medical advice Remove and wash/dispose of contaminated clothing promptly.

Overdose Treatment

If symptomatic hypotension should occur, supportive treatment should be instituted. Telmisartan is not removed by hemodialysis.

Section 5. Fire - fighting measures

Flash point	Not Found	**Upper Flammable Limit:**	Not Found
Auto-Ignition Temperature:	Not Found	**Lower Flammable Limit:**	Not Found
Extinguishing Media	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.	**Fire and Explosion Hazard**	This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build up of static electricity.

Fire Fighting Procedure

As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.

Section 6. Accidental Release Measures

Spill Response

Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

Section 7. Handling and Storage

Storage	Store at 20° to 25°C (68° to 77°F). Protect from moisture. Tablets should not be removed from blisters until immediately before administration.
Incompatibilities	No Data Available.

Section 8. Exposure controls / personal protection

Respiratory Protection	Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.
Skin Protection	Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.
Eye protection	Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.
Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.
Engineering controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Section 9. Physical and chemical properties

Appearance	Telmisartan Tablets USP, 20 mg are mottled light brown to mottled brown-colored, round-shaped, flat face beveled edge, uncoated tablets debossed with '471' on one side and plain on the other side. Telmisartan Tablets USP, 40 mg are mottled light brown to mottled brown-colored, oblong-shaped, biconvex, uncoated tablets debossed with '472' on one side and plain on the other side. Telmisartan Tablets USP, 80 mg are mottled light brown to mottled brown-colored, oblong-shaped, biconvex, uncoated tablets debossed with '473' on one side and plain on the other side

Solubility in water	Insoluble in water, slightly soluble in methanol, sparingly soluble in methylene chloride. It dissolves in 1M sodium hydroxide.	**Odour**	No Data Available
Boiling point	No Data Available	**Melting Point**	No Data Available
Evaporation rate	No Data Available	**Vapour density**	No Data Available
Reactivity in water	No Data Available	**Evaporation rate**	No Data Available
Percentage Volatile by volume	No Data Available	**Specific gravity**	No Data Available
Vapour pressure	No Data Available	**Other information**	Not Applicable

Section 10. Stability and Reactivity

Condition to avoid	Avoid exposure to extreme heat, light and moisture.	**Stable**	Stable under Controlled Room Temperature.
Decomposition Products	No Data Available	**Hazardous Reaction**	No data available.
Incompatibilities	No data available.		

Section 11. Toxicological information

General	Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.
Target organ	Eye contact, Skin contact and inhalation is not great risk as this product is tablet.
Other	Not Applicable

Section 12. Ecological information

Do not allow product to enter drinking water supplies, waste water or soil.

Section 13. Disposal Consideration

Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea(IMDG).

Section 15. Regulatory Information

Generic Medicine. Approved by USFDA & the ANDA Number is 203325

Section 16. Other information

None

Date of issue: 28/05/2015 **Supersedes edition of:** 02

The information contained herein is based on the state of our knowledge. It Characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.