

**SAFETY DATA SHEET**

Section 1: Identification	
<b>Product Name</b>	Olmesartan and Hydrochlorothiazide Tablets 20 mg /12.5 mg,40 mg/12.5 mg and 40 mg/25 mg
<b>Recommended use</b>	Pharmaceutical use
<b>Manufacturer</b>	Hetero Labs Limited Unit V, Survey. No 439, 440, 441 & 458, Polepally Village, Mahabubnagar, Telangana 509301, India
<b>Distributor</b>	<b>Camber Pharmaceuticals, Inc., Piscataway, NJ 08854</b>
Section 2: Hazard(s) Identification	
<b>Hazard Statements</b>	If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air. May damage the unborn child. Causes damage to organs (Kidney, Parathyroid gland) through prolonged or repeated exposure
<b>Precautionary Statements</b>	<b>Prevention:</b> Do not breathe dust. Wash skin thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves, protective clothing, eye protection and face protection <b>Response:</b> If exposed or concerned: Get medical attention <b>Disposal:</b> Dispose of contents and container to an approved waste disposal plant.
<b>Other hazards</b>	Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin.
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Olmesartan Medoxomil	144689-63-4
Lactose monohydrate	64044-51-5
Microcrystalline Cellulose	9004-34-6

Low substituted hydroxyl propyl cellulose	9004-64-2
Hydroxy Propyl Cellulose	9004-64-2.
Hydrochlorothiazide	58-93-5
Lactose Monohydrate	64044-51-5
Magnesium Stearate	557-04-0
Opadry Pink	NA
Opadry Beige	NA
Hypromellose	9004-65-3
Titanium dioxide	9004-65-3
Talc	14807-96-6
Iron oxide yellow	51274-00-1
Iron oxide red	1309-37-1

#### Section 4: First-Aid Measures

<b>General advice</b>	In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.
<b>Eye contact</b>	If in eyes, rinse well with water. Get medical attention if irritation develops and persists
<b>Skin Contact</b>	In case of contact, immediately flush skin with soap and plenty of water, Remove contaminated clothing and shoes, Get medical attention, Wash clothing before reuse, Thoroughly clean shoes before reuse.
<b>Inhalation</b>	If inhaled, remove to fresh air. Get medical attention.
<b>Most important symptoms and effects, both acute and delayed</b>	May damage the unborn child. Causes damage to organs through prolonged or repeated exposure. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.
<b>Protection of first-aiders</b>	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists.
<b>Notes to physician</b>	Treat symptomatically and supportively.

#### Section 5: Fire-Fighting Measures

<b>Suitable extinguishing Media</b>	Use carbon dioxide, dry chemical, or water spray, Alcohol-resistant foam
-------------------------------------	--

<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards during fire fighting</b>	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
<b>Hazardous Combustion Products</b>	Carbon oxides, Nitrogen oxides (NOx), Chlorine compounds, Sulfur oxides
<b>Specific extinguishing methods</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area
<b>Special protective equipment for fire-fighters</b>	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

### Section 6: Accidental Release Measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendation.
<b>Environmental precautions</b>	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
<b>Methods and materials for containment and cleaning up</b>	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.

### Section 7: Handling and Storage

<b>General Handling</b>	Do not get on skin or clothing. Do not breathe dust. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
-------------------------	---

	<p>Minimize dust generation and accumulation.          Keep container closed when not in use.          Keep away from heat and sources of ignition.          Take precautionary measures against static discharges.          Do not eat, drink or smoke when using this product.          Take care to prevent spills, waste and minimize release to the environment.</p>
<b>Storage Conditions</b>	Store at 20° to 25° C (68° to 77°F) [see USP Controlled Room Temperature].

### Section 8: Exposure Controls/Personal Protection

<b>Engineering measures</b>	<p>All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).          Minimize open handling.</p>
-----------------------------	---

#### **Personal Protective Equipment**

<b>Respiratory protection</b>	<p>General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.</p>
<b>Eyes</b>	<p>Wear safety glasses with side shields or goggles.          If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.</p>
<b>Skin and body protection</b>	<p>Work uniform or laboratory coat.          Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.          Use appropriate degowning techniques to remove potentially contaminated clothing</p>

### Section 9: Physical and Chemical Properties

<b>Appearance</b>	Tablet
<b>Description</b>	Olmesartan medoxomil and hydrochlorothiazide tablets, 20 mg/12.5 mg are reddish-yellow, round, biconvex film-

	<p>coated tablets debossed with 'H' on one side and 'O5' on the other side. They are supplied as follows:</p> <p>Bottles of 30 tablets                      NDC 31722-886-30          Bottles of 90 tablets                      NDC 31722-886-90          Carton of 100 (10 x 10)          Unit dose tablets                              NDC 31722-886-32</p> <p>Olmesartan medoxomil and hydrochlorothiazide tablets 40 mg/12.5 mg are reddish-yellow, oval, biconvex film-coated tablets debossed with 'H' on one side and 'O7' on the other side. They are supplied as follows:</p> <p>Bottles of 30 tablets                      NDC 31722-887-30          Bottles of 90 tablets                      NDC 31722-887-90          Carton of 100 (10 x 10)          Unit dose tablets                              NDC 31722-887-32</p> <p>Olmesartan medoxomil and hydrochlorothiazide tablets, 40 mg/25 mg are pink, oval, biconvex film-coated tablets debossed with 'H' on one side and 'O8' on the other side. They are supplied as follows:</p> <p>Bottles of 30 tablets                      NDC 31722-888-30          Bottles of 90 tablets                      NDC 31722-888-90          Carton of 100 (10 x 10)          Unit dose tablets                              NDC 31722-888-32</p> <p><b>Storage</b>          Store at 20° to 25° C (68° to 77°F) [see USP Controlled Room Temperature].</p>
--	--

**Section 10: Stability and Reactivity**

<b>Reactivity</b>	Not classified as a reactivity hazard
<b>Chemical stability</b>	Stable under normal conditions.
<b>Possibility of hazardous reactions</b>	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
<b>Conditions to avoid</b>	Heat, flames and sparks. Avoid dust formation
<b>Incompatible materials</b>	Oxidizing agents
<b>Hazardous decomposition products</b>	No hazardous decomposition products are known.

**Section 11: Toxicological Information**

<b>Information on likely routes of exposure</b>	
Inhalation	
Skin contact	
Ingestion	
Eye contact	

**Acute toxicity**

Not classified based on available information.

**Product:**

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

**Components:**

**Olmesartan:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
LD50 (Mouse): > 2,000 mg/kg  
LD50 (Dog): > 1,500 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

**Hydrochlorothiazide:**

Acute oral toxicity : LD50 (Rat): > 2,750 mg/kg  
LD50 (Mouse): > 2,830 mg/kg

Acute inhalation toxicity : LD50 (Rat): 990 mg/kg  
Application Route: Intravenous  
LD50 (Mouse): 590 mg/kg  
Application Route: Intravenous

**Skin corrosion/irritation**

Not classified based on available information

**Components:**

**Olmesartan:**

Remarks : No data available

**Hydrochlorothiazide:**

Species : Rabbit

Result : No skin irritation

**Serious eye damage/eye irritation:**

Not classified based on available information

**Components:**

**Olmesartan:**

Species : Rabbit

Result : Moderate eye irritation

Method : Draize Test

**Hydrochlorothiazide:**

Species	: Rabbit
Result	: Mild eye irritation
<b><u>Respiratory or skin sensitization:</u></b>	
<b>Skin sensitization</b>	
Not classified based on available information.	
<b>Respiratory sensitization</b>	
Not classified based on available information	
<b><u>Components:</u></b>	
<b>Olmesartan</b>	
Routes of exposure	: Skin contact
Remarks	: No data available
<b>Germ cell mutagenicity</b>	
Not classified based on available information.	
<b><u>Components:</u></b>	
<b>Olmesartan:</b>	
Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: Mutagenicity (in vitro mammalian cytogenetic test) Result: Negative Test Type: : Chromosome aberration test in vitro Test system: Chinese hamster lung cells Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	: Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Application Route: Oral Result: negative
Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.	
<b>Hydrochlorothiazide:</b>	
Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative

Test Type: Chromosomal aberration  
Test system: Chinese hamster ovary cells  
Result: negative

Test Type: : Chromosome aberration  
Test system: Chinese hamster ovary cells  
Result: Positive

Test Type: : in vitro test  
Test system: mouse lymphoma cells  
Result: positive

Genotoxicity in vivo

: Test Type: Chromosomal aberration  
Species: Chinese hamster  
Cell type: Bone marrow  
Result: negative

Test Type: in vivo assay  
Species: Mouse  
Cell type: Bone marrow  
Result: negative

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

**Carcinogenicity:** Not classified based on available information.

**Components:**

**Olmesartan:**

Species : Rat  
Application Route : Oral  
Exposure time : 2 Years  
Result : negative

Species : Mouse  
Application Route : Oral

Exposure time	: 6 Months
Result	: negative
<b>Hydrochlorothiazide:</b>	
Species	: Mouse, female
Application Route	: Oral
Exposure time	: 2 Years
Result	: equivocal
Species	: Mouse, male
Application Route	: Oral
Exposure time	: 2 Years
Result	: equivocal
Species	: Rat, male and female
Application Route	: Oral
Exposure time	: 2 Years
Result	: negative
<b>IARC</b>	Group 2B: Possibly carcinogenic to humans Hydrochlorothiazide
<b>OSHA</b>	No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.
<b>NTP</b>	No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
<b>Reproductive toxicity</b>	
May damage the unborn child	
<b><u>Components:</u></b>	
<b>Olmesartan:</b>	
Effects on fertility	: Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 1,000 mg/kg body weight Result: No effects on fertility.
Effects on fetal development	: Test Type: Development Species: Rat Application Route: Oral Dose: 1000 milligram per kilogram

Result: No teratogenic effects.

Test Type: Development

Species: Rabbit

Application Route: Oral

Developmental Toxicity: LOAEL:  $\geq$  1.6 mg/kg body weight

Symptoms: Malformations were observed., Reduced body weight

Result: Effects on postnatal development.

Reproductive toxicity – Assessment : Positive evidence of adverse effects on development from human epidemiological studies.

**Hydrochlorothiazide:**

Effects on fertility

: Test Type: Fertility

Species : Rat, male and female

Application Route: oral (feed)

Fertility: NOAEL: 4 mg/kg body weight

Result: Effects on fertility.

Test Type: Fertility

Species: Mouse, male and female

Application Route: Ingestion

Fertility: NOAEL:100 mg/kg body weight

Result: Effects on fertility.

Effects on fetal developoment

: Test Type: Development

Species : Mouse

Application Route: oral

Developmental Toxicity: NOAEL: 3,000 mg/kg body weight

Result: Effects on fertility.

Test Type: Development

Species: Mouse

Application Route: Oral

Developmental Toxicity: NOAEL: 3,000 mg/kg body

Result: No teratogenic effects

**STOT-single exposure:**

Not classified based on available information

**STOT-repeated exposure:**

Causes damage to organs (Kidney, Parathyroid gland) through prolonged or repeated exposure.

**Components:**

**Hydrochlorothiazide:**

Target Organs : Kidney, Parathyroid gland  
 Assessment : Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity:**

**Components:**

**Olmesartan:**

Species : Rat  
 NOAEL : 2,000 mg/kg  
 Application Route : Oral  
 Exposure time : 24 Months  
 Remarks : No significant adverse effects were reported

**Hydrochlorothiazide:**

Species : Rat, male and female  
 LOAEL : 10 mg/kg  
 Application Route : Oral  
 Exposure time : 2 Years  
 Target Organs : Kidney, Parathyroid gland

Species : Mouse, male and female  
 LOAEL : 300 - 550 mg/kg  
 Application Route : Oral  
 Exposure time : 2 Years  
 Remarks : No significant adverse effects were reported

Species : Dog  
 : 50 - 200 mg/kg  
 Application Route : Oral  
 Exposure time : 9 Months  
 Target Organs : Parathyroid gland

<p><b>Aspiration toxicity</b> Not classified based on available information.</p> <p><b><u>Components:</u></b></p> <p><b>Hydrochlorothiazide:</b> No aspiration toxicity classification</p> <p><b>Experience with human exposure</b></p> <p><b><u>Components:</u></b></p> <p><b>Olmesartan:</b> Eye contact : Symptoms: Eye irritation Ingestion : Symptoms: hypotension Remarks: May cause harm to the unborn child. Based on Human Evidence</p> <p><b>Hydrochlorothiazide:</b> Eye contact : Symptoms: Eye irritation Ingestion : Symptoms: Dizziness, Headache, Fatigue, Nausea, Abdominal pain, hypotension, dry mouth, electrolyte imbalance, eye pain.</p>	
<p><b>Section 12: Ecological Information</b></p>	
<p><b>Ecotoxicity</b></p>	
<p><b>Hydrochlorothiazide:</b> Toxicity to fish</p> <p>Toxicity to daphnia and other aquatic invertebrates</p>	<p>LC50 (Pimephales promelas (fathead minnow)): &gt; 500 mg/l Exposure time: 96 h</p> <p>EC50 (Daphnia magna (Water flea)): &gt; 500 mg/l Exposure time: 48 h</p>
<p><b>Persistence and degradability</b></p>	
<p><b>Cellulose:</b> Biodegradability</p>	<p>Result: Readily biodegradable</p>
<p><b>Hydrochlorothiazide:</b> Stability in water</p>	<p>Hydrolysis: 46.2 %(96 h)</p>
<p><b>Bioaccumulative potential</b></p>	<p>No data available</p>
<p><b>Mobility in soil</b></p>	<p>No data available</p>
<p><b>Other adverse effects</b></p>	<p>No data available</p>

Section 13: Disposal Considerations	
<b>Waste Treatment Methods</b>	
<b>Waste from residues</b>	Dispose of in accordance with local regulations.
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.
Section 14: Transport Information	
<b>International Regulations</b>	
<b>UNRTDG</b>	Not regulated as a dangerous good
<b>IATA-DGR</b>	Not regulated as a dangerous good
<b>MDG-Code</b>	Not regulated as a dangerous good
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not regulated as a dangerous good
<b>Domestic regulation</b>	
<b>49 CFR</b>	Not regulated as a dangerous good
Section 15: Regulatory Information	
<b>CERCLA Reportable Quantity</b>	This material does not contain any components with a CERCLA RQ
<b>SARA 304 Extremely Hazardous Substances Reportable Quantity</b>	This material does not contain any components with a section 304 EHS RQ.
<b>SARA 302 Extremely Hazardous Substances Threshold Planning Quantity</b>	This material does not contain any components with a section 302 EHS TPQ
<b>SARA 311/312 Hazards</b>	This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
<b>US State Regulations</b>	
<b>Pennsylvania Right To Know</b>	
Olmesartan	144689-63-4
Hydrochlorothiazide	58-93-5
<b>The ingredients of this product are reported in the following inventories:</b>	
AICS :	not determined
DSL :	not determined
IECSC :	not determined

## Section 16: Other Information

**Issue Date** : 17-02-2026

**Version** : 00

### **Further information**

Revision date: NA

Revision note: NA

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. 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.

Hetero Labs Limited Unit-V shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero Labs Limited Unit-V reserves the right to revise this SDS.