

SAFETY DATA SHEET

 Date: 10/01/2018

Generic Name: Olmesartan Medoxomil Tablets, USP 5 mg, 20 mg, 40 mg.

Brand Equivalent: Benicar® (Olmesartan Medoxomil) Tablets, 5 mg, 20 mg, 40 mg.

SECTION 1: IDENTIFICATION	
Product Name	Olmesartan Medoxomil Tablets
Active substance	Olmesartan Medoxomil
Synonyms	N/A
Formula	For Olmesartan Medoxomil C ₂₉ H ₃₀ N ₆ O ₆
Intended Use	Olmesartan Medoxomil is used in the treatment of hypertension, to lower blood pressure or combination therapy for the management of hypertension. It may be used alone or in combination with other antihypertensive agents.
Chemical Name	For Olmesartan Medoxomil: (5-methyl-2-oxo-2 <i>H</i> -1,3-dioxol-4-yl)methyl 4-(2-hydroxypropan-2-yl)-2-propyl-1-({4-[2-(2 <i>H</i> -1,2,3,4-tetrazol-5-yl)phenyl]phenyl}methyl)-1 <i>H</i> -imidazole-5-carboxylate
How Supplied	5 mg: Yellow, round, film coated tablets, debossed with '339' on one side and 'SG' on other side. 20 mg: White, round, film coated tablets, debossed with 'SG' on one side and '340' on other side. 40 mg: White to off white, Oval Shape, film coated tablets, debossed with 'SG' on one side and '341' on other side.
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723

2. HAZARDS IDENTIFICATION	
Fire & Explosion:	Expected to be non-combustible.
Health:	Do not use in patients with known hypersensitivity to any component.
Environment	No information is available about the potential of this product to produce adverse environmental effects.

3. Composition/Information on ingredients		
Components	CAS-No	Concentration (%w/w)
Olmesartan Medoxomil, USP *	144689-63-4	5 mg: 9.30 % 20 mg: 9.30 % 40 mg: 9.30%
Silicified Microcrystalline Cellulose, NF (Prosolv SMCC 50)	9004-34-6	*
Lactose Monohydrate, NF (SuperTab 11 SD)	64044515	*
Croscarmellose Sodium, NF (VIVASOL® GF)	74811657	*
Pregelatinized Starch, NF (Starch 1500)	9005-25-8	*
Silicified Microcrystalline Cellulose, NF (Prosolv SMCC 50)	9004-34-6	*
Magnesium Stearate, NF	557040	*
Opadry Yellow (03F82726)	Mixture	*
Opadry White (03F180003)	Mixture	*

* Proprietary, In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret. **Present in trace amounts.

^b Complies with the 21 CFR 73.1200 requirement of NMT 5 mg elemental iron / day.

4. FIRST AID MEASURES	
Ingestion	After intentional swallowing, induce vomiting only if fully conscious. Rinse out mouth and give plenty of water to drink. Seek medical advice.
Inhalation	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
Skin Contact	Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.
Eye Contact	Flush eyes with plenty of water. Get medical attention.
NOTES TO HEALTH PROFESSIONALS	
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.
OVERDOSAGE	Limited data are available related to over dosage in humans. The most likely manifestations of over dosage would be hypotension and tachycardia; bradycardia could be encountered if parasympathetic (vagal) stimulation occurs. If symptomatic hypotension should occur, supportive treatment should be initiated. The dialyzability of Olmesartan is unknown.

5. FIRE-FIGHTING MEASURES	
Suitable extinguishing media	Extinguish fires with CO ₂ , extinguishing powder, foam, or Water spray.
Hazardous Combustion Products:	Hazardous combustion or decomposition products are expected when the product is exposed to fire.
Special Fire Fighting Procedures	For single units (Packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.
Fire / Explosion Hazards:	Assume that this product is capable of sustaining combustion.

6. ACCIDENTAL RELEASE MEASURES	
Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Clean-up Methods	Collect and place it in a suitable, properly labeled container for recovery or disposal.
Measures for Environmental Protections	For large spills, take precautions to prevent entry into water ways sewers, or surface drainage systems.
Additional Consideration for Large Spills	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE	
General Handling	No special control measures required for the normal handling of this product.
Storage Conditions	Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F). [See USP Controlled Room Temperature.] Protect from moisture.

8. Exposure controls/Personal protection	
Exposure controls/personal protection	Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES	
General Information	
<i>Appearance</i> Physical State Color Form Molecular Formula	Coated tablets 5 mg: Yellow; 20 mg: White & 40 mg: White Tablets Mixture
<i>Odour</i> Odour Odor Threshold	Not available Not available
pH	Not available
Melting/Freezing Point (°C)	Not available
Boiling Point (°C)	Not available
Log Octanol/Water Partition Coeff [log Kow]	Not available
Evaporation rate	Not available
Viscosity	Not available
Vapor Pressure	Not available
Vapor Density	Not available
Relative Density	Not available
Decomposition Temperature (°C)	Not available
<i>Other information</i>	
Bulk density	Not available
Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Molecular Weight	Mixture
Surface Tension	Not available
pKa	Not available
Particle Size	Not available
Specific Gravity/ Relative Density	Not available
% Volatile	Not available
<i>Thermal/Stability properties</i>	
Autoignition temperature	Not available
Explosive Limits, LEL	Not available
Explosive limits, UEL	Not available
Flammability (Solids)	Not available
Flash point	Not available
Oxidizing Potential	Not available
Vapor Pressure	Not available
Saturated Vapor Concentration	Not available

10. Stability and Reactivity	
Stability and Reactivity	Stable under recommended storage conditions.

11. Toxicological Information	
Carcinogenesis, Mutagenesis, Impairment of Fertility	Carcinogenicity not determined. Mutagenicity not determined. Impairment of fertility not determined.

12. Ecological Information	
No relevant studies identified.	

13. Disposal considerations	
Incinerate in an approved facility. Follow all federal state and local environmental regulations.	

14. Transport Information	
IATA/ICAO - Not Regulated	
IATA Proper shipping Name	NA
IATA UN/ID No	NA
IATA Hazard Class	NA
IATA Packaging Group	NA
IATA Label	NA
IMDG - Not Regulated	
IMDG Proper shipping Name	NA
IMDG UN/ID No	NA
IMDG Hazard Class	NA
IMDG Flash Point	NA
IMDG Label	NA
DOT - Not Regulated	
DOT Proper shipping Name	NA
DOT UN/ID No	NA
DOT Hazard Class	NA
DOT Flash Point	NA
DOT Packing Group	NA
DOT Label	NA

15. Regulatory Information	
This Section Contains Information relevant to compliance with other Federal and/or state laws.	

16. Other information	
Recommended Restrictions for Use:	Not available
Prepared on	<i>10/01/2018</i>
Revision	00
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