

SAFETY DATA SHEET

 Date: 08/02/21

Generic Name: Metformin hydrochloride Extended-Release Tablets USP 500 mg & 1000 mg.

 Brand Equivalent: Fortamet[®] (metformin hydrochloride) extended-release tablets, 500 mg and 1000 mg

SECTION 1: IDENTIFICATION	
Product Name	Metformin hydrochloride Extended-Release Tablets USP 500 mg & 1000 mg
Active substance	Metformin hydrochloride
Synonyms	N/A
Formula	C ₄ H ₁₁ N ₅ •HCl
Intended Use	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Chemical Name	N,N-dimethylimidodicarbonimidic diamide hydrochloride
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723

2. HAZARDS IDENTIFICATION	
Fire and Explosion	Assume that this product is capable of sustaining combustion.
Health	Metformin is contraindicated in patients with renal disease or renal dysfunction (e.g., as suggested by serum creatinine levels ≥ 1.5 mg/dL [males], ≥ 1.4 mg/dL [females] or abnormal creatinine clearance) which may also result from conditions such as cardiovascular collapse (shock), acute myocardial infarction, and septicemia. Known hypersensitivity to metformin. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin. Metformin should be temporarily discontinued in patients undergoing radiologic studies involving intravascular administration of iodinated contrast materials, because use of such products may result in acute alteration of renal function

3. Composition/Information on ingredients		500 mg	1000 mg
Components	CAS-No	Concentration (%w/w)	
Metformin Hydrochloride	1115-70-4	72.43%	
Povidone, USP (K-30)	9003-39-8	*	
Povidone, USP (K-90)	9003-39-8	*	
Crospovidone, NF	9003-39-8	*	
Pregelatinized Starch, NF	9005-25-8	*	
Magnesium Stearate, NF	557-04-0	*	
Hypromellose, USP (Methocel K100 Premium LV CR)	9004-65-3	*	
Hypromellose, USP (Methocel K100M Premium CR grade)	9004-65-3	*	
Silicon Dioxide, NF (Syloid 244FP)	7631-86-9	*	
Ammonio methacrylate copolymer dispersion, Type A, NF (Eudragit RL30D)	33434241	*	
Ammonio methacrylate copolymer dispersion, Type-B, NF(Eudragit RS30D)	33434241	*	
Talc, USP (140)	14807966	*	
Triethyl Citrate, NF	77930	*	
Sheffcoat White 04	Mixture	*	

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

4. FIRST AID MEASURES	
Ingestion	If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention.
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	Hypoglycemia has not been seen even with ingestion of up to 85 grams of immediate-release metformin, although lactic acidosis has occurred in such circumstance. Metformin is dialyzable with a clearance of up to 170 mL/min under good hemodynamic conditions. Therefore, hemodialysis may be useful for removal of accumulated drug from patients in whom metformin over-dosage is suspected.

5. FIRE-FIGHTING MEASURES	
Fire and explosion hazards	Assume that this product is capable of sustaining combustion.
Extinguishing media	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
Special firefighting procedures	For single units (packages): No special requirements needed.
Hazardous combustion products	Hazardous combustion or decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES	
Personal precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up methods	Collect and place it in a suitable, properly labeled container for recovery or disposal.

7. HANDLING AND STORAGE	
Handling	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
Storage	Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature]. Keep tightly closed (protect from moisture). Protect from light. Avoid excessive heat and humidity.

8. 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	
Appearance	Film coated tablets
Physical State	
Color	500 mg - White to off white Oval shape tablets
Form	1000 mg - White to off white Oval shape tablets

10. Stability and Reactivity	
Stable under recommended storage conditions	

11. Toxicological Information

**Carcinogenesis, Mutagenesis,
Impairment of Fertility:**

Long-term carcinogenicity studies with metformin have been performed in rats (dosing duration of 104 weeks) and mice (dosing duration of 91 weeks) at doses up to and including 900 mg/kg/day and 1500 mg/kg/day, respectively. These doses are both approximately four times the maximum recommended human daily dose of 2000 mg based on body surface area comparisons. No evidence of carcinogenicity with metformin was found in either male or female mice. Similarly, there was no tumorigenic potential observed with metformin in male rats. There was, however, an increased incidence of benign stromal uterine polyps in female rats treated with 900 mg/kg/day.

There was no evidence of mutagenic potential of metformin in the following *in vitro* tests: Ames test (*S. typhimurium*), gene mutation test (mouse lymphoma cells), or chromosomal aberrations test (human lymphocytes). Results in the *in vivo* mouse micronucleus test were also negative. Fertility of male or female rats was unaffected by metformin when administered at doses as high as 600 mg/kg/day, which is approximately three times the maximum recommended human daily dose based on body surface area comparisons.

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 : N/A
 IATA UN/ID No : N/A
 IATA Hazard Class : N/A
 IATA Packaging Group : N/A
 IATA Label : N/A

IMDG - Not Regulated

IMDG Proper shipping Name : N/A
 IMDG UN/ID No : N/A
 IMDG Hazard Class : N/A
 IMDG Flash Point : N/A
 IMDG Label : N/A

DOT - Not Regulated

DOT Proper shipping Name : N/A
 DOT UN/ID No : N/A
 DOT Hazard Class : N/A
 DOT Flash Point : N/A
 DOT Packing Group : N/A
 DOT Label : N/A

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	08/02/21
Revision	00
Disclaimer	The above information is believed to be correct but should only be used as a guide. ScieGen Pharmaceuticals, Inc. disclaims any express or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental or consequential damages resulting from reliance on the above information.