

SAFETY DATA SHEET

Section 1: Identification	
Material	Metformin HCl Oral solution 500 mg/5mL
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
Distributor	Camber Pharmaceuticals, Inc. , Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Fire and Explosion	Expected to be non-combustible
Health	Metformin hydrochloride extended-release tablets are contraindicated in patients with: Renal impairment (e.g., serum creatinine levels > 1.5 mg/dL for men, > 1.4 mg/dL for women or abnormal creatinine clearance), which may also result from conditions such as cardiovascular collapse (shock), acute myocardial infarction, and septicemia. Known hypersensitivity to metformin hydrochloride. Acute or chronic metabolic acidosis, including diabetic ketoacidosis. Diabetic ketoacidosis should be treated with insulin.
Environment	No information is available about the potential of this product to produce adverse environmental effects.
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Metformin Hydrochloride	1115-70-4
Potassium Bicarbonate	298-14-6
Hydrochloric acid	7647-01-0
Xylitol	87-99-0
Sucralose	56038-13-2
ART Cherry flavor	NA
Section 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	
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
Over dosage	<p>No cases of overdose were reported during metformin hydrochloride extended-release tablets clinical trials. It would be expected that adverse reactions of a more intense character including epigastric discomfort, nausea, and vomiting followed by diarrhea, drowsiness, weakness, dizziness, malaise and headache might be seen. Should those symptoms persist, lactic acidosis should be excluded.</p> <p>Overdose of metformin hydrochloride has occurred, including ingestion of amounts greater than 50 grams. Hypoglycemia was reported in approximately 10% of cases, but no causal association with metformin hydrochloride has been established. Lactic acidosis has been reported in approximately 32% of metformin overdose cases. 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 overdosage is suspected.</p>
Section 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	<p>For single units (packages): No special requirements needed.</p> <p>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.</p>
Hazardous Combustion Products	Hazardous combustion or decomposition products are expected when the product is exposed to fire.
Section 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.
Section 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].
Section 8: Exposure Controls/Personal Protection	
Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.	
Section 9: Physical and Chemical Properties	
Physical Form	Solution
Colour	Clear, colorless solution
Flavour	Cherry
Description	Metformin hydrochloride oral solution 500 mg per 5 mL (100 mg/mL) oral solution is supplied in bottles with child-resistant caps and a dosing cup as follows: 16 ounce (473 mL) 31722-042-47
Section 10: Stability and Reactivity	
Stable under recommended storage conditions	
Section 11: Toxicological Information	
Carcinogenesis, Mutagenesis, Impairment of Fertility	
<p>Long-term carcinogenicity studies have been performed in Sprague Dawley rats at doses of 150, 300, and 450 mg/kg/day in males and 150, 450, 900, and 1200 mg/kg/day in females. These doses are approximately 2, 4, and 8 times in males, and 3, 7, 12, and 16 times in females of 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 rats. A carcinogenicity study was also performed in Tg.AC transgenic mice at doses up to 2000 mg applied dermally. No evidence of carcinogenicity was observed in male or female mice.</p> <p>Genotoxicity assessments in the Ames test, gene mutation test (mouse lymphoma cells), chromosomal aberrations test (human lymphocytes) and <i>in vivo</i> mouse micronucleus tests were negative. Fertility of male or female rats was not affected by metformin when administered at dose up to 600 mg/kg/day, which is approximately 3 times the maximum recommended human daily dose based on body surface area comparisons.</p>	
Section 12: Ecological Information	
No relevant studies identified.	
Section 13: Disposal Considerations	
Incinerate in an approved facility. Follow all federal state and local environmental regulations	

Section 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

Section 15: Regulatory Information

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

Section 16: Other Information

Issue Date: 26-06-2025

Version: 00

Further information

Revision Date: New issue

Revision Note: New issue

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.

Annora Pharma Private Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Annora Pharma Private Limited reserves the right to revise this SDS.