SAFETY DATA SHEET

Metformin Hydrochloride Extended-Release Tablets, USP 500 mg and 1000 mg

EMERGENCY OVERVIEW

METFORMIN HYDROCHLORIDE EXTENDED-RELEASE TABLETS, USP contain an active drug substance metformin hydrochloride, USP and pharmaceutical excipients generally considered safe, non-toxic and non-hazardous. The quantities of the excipients used in the product are well within the IID (Inactive Ingredient Database) limits prescribed by USFDA for oral tablets.

WARNING: Ingestion of large amounts may be harmful.

Section 1. Identification of the substance

Identification of the product

Product name	**:**	Metformin Hydrochloride Extended-Release Tablets, USP
Potencies	**:**	500 mg and 1000 mg
Chemical Name	**:**	N, N-dimethylimidodicarbonimidic diamide hydrochloride
Therapeutic Category	**:**	Anti-diabetic
Product Use	**:**	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
Marketed by	**:**	**Ajanta Pharma USA Inc**. Bridgewater, NJ 08807
Manufactured by	**:**	**Ajanta Pharma Limited** B-4/5/6, MIDC area, Paithan, Aurangabad 431148**,** Maharashtra, India.
Contact Information	**:**	855-664-7744

Section 2. Health hazards information

Potential Health Effects	**:**	**Inhalation:** Not expected to be hazardous in final pharmaceutical form. **Eye Contact**: Not expected to be hazardous in final pharmaceutical form. **Skin Contact:** Not expected to be hazardous in final pharmaceutical form.

Ingestion: Health injuries are not known or expected under normal use. Exposures above clinical dosage could result in adverse effects. Minor occupational exposures are not expected to be harmful.
Other: 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. 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.

Effects of Overexposure : The potential for exposure is reduced in finished pharmaceutical form.

Section 3. Composition / information on ingredients

Active ingredient	**Exposure Limit**	**CAS No.**
Metformin hydrochloride, USP	TWA: 0.8 mg/m^3	1115-70-4

Inactive ingredients: Each tablet contains the following inactive ingredients: hypromellose, magnesium stearate, polyethylene glycol (PEG 400), povidone, pregelatinized starch, ethyl cellulose. Imprinting ink contains: shellac, ferrosoferric oxide, propylene glycol and ammonium hydroxide.

Section 4. First aid measures

This product in the final dosage form (tablets) does not pose a problem of exposure to active moiety, and does not cause inhalation, skin and eye irritation problem. The lose powder exposure hazards are during the manufacturing process.

Eye Contact : Immediately flush eyes with water for at least 15 minutes. Get medical attention.

Skin Contact : Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if skin reaction occur. Wash clothing before reuse.

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. If not breathing, give artificial respiration or oxygen by trained personnel. Get immediate medical attention immediately.
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.

Section 5. Fire-fighting measures

Flash Point	**:**	Not Available.
Extinguishing Media	**:**	Water spray, carbon dioxide, dry chemical powder or appropriate foam
General Fire Hazards/ Hazardous Combustible Products	**:**	Hazardous combustion or decomposition products are expected when the product is exposed to fire.
Special Fire Fighting Procedures	**:**	Wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

Section 6. Accidental release measures

Personal Precautions	**:**	Personnel involved in clean-up should wear appropriate personal protective equipment with the degree of hazard. Minimize exposure.
Environmental Protections	**:**	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release. For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	**:**	Wipe up with a damp cloth and place in container for disposal. Avoid generating airborne dust. Clean spill area thoroughly. Prevent discharge to drains.
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.

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 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Avoid excessive heat and humidity. Keep tightly closed (protect from moisture). Protect from light.

Section 8. Exposure controls/personal protection

Exposure Limits : TWA: 0.8 mg/m^3

Engineering Controls : For consumer use, no unusual precaution are necessary for handling packets. In laboratory, medical or industrial setting use appropriate ventilation.

Respiratory Protection : For consumer use, no unusual precaution are necessary. However, for handling packets, in laboratory, medical or industrial setting use NIOSH approved respirators for protection if necessary.

Personal Protection : For consumer use, no unusual precaution are necessary. However, for handling packets in laboratory, medical or industrial setting use gloves as recommended. Wear appropriate clothing to avoid skin contact

Recommended Facilities : None

Section 9. Physical and chemical properties

Appearance : **Metformin Hydrochloride Extended-Release Tablets, USP 500 mg** are white to off-white colored, oval shaped, beveled edged, unscored biconvex shaped, film-coated extended-release tablets imprinted with "ME1" in black ink on one side and plain on the other side. (Bottles of 60 with child-resistant closure - NDC 27241-188-60)

Metformin Hydrochloride Extended-Release Tablets, USP 1000 mg are white to off-white colored, oval shaped, unscored biconvex-shaped, film-coated extended-release tablets imprinted with "ME2" in black ink on one side and plain on the other side. (Bottles of 60 with child-resistant closure - NDC 27241-189-60)

Other Information	**:**	Metformin hydrochloride USP is a white crystalline powder that is freely soluble in water and practically insoluble in acetone, ether and chloroform. The pKa of metformin are 12.4 The pH of a 1% aqueous solution of metformin hydrochloride is 6.68.

Section 10. Stability and reactivity

Stability	**:**	Stable under recommended storage conditions
Incompatibility	**:**	Strong oxidizing agents. Alkalis.
Hazardous Decomposition	**:**	Hazardous decomposition products formed under fire conditions: carbon oxides (COx), nitrogen oxides (NOx) and gaseous hydrogen chloride (HCl).
Conditions to Avoid	**:**	Direct sunlight. Extremely high or low temperatures.

Section 11. Toxicological information

Acute toxicity	**:**	Oral LD50 (rat) : 1000 mg/kg
Carcinogenesis	**:**	None of the components of this product are suspected to be a carcinogen.
Mutagenesis	**:**	When processed and used as directed, this product is not expected to produce mutagenic effects.
Fertility effects	**:**	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.

Section 12. Ecological information

Eco toxicity of drug substance	**:**	Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.
In the finished product form	**:**	There is no potential for air borne contamination since the drug substance is in consolidated form as tablets.

Section 13. Disposal Consideration

Waste Disposal Considerations: Dispose the material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended. At home: If pharmacy service available, return unused tablets to pharmacy for disposal. Discard away from children's reach.

Section 14. Transport information

This product is not subject to the regulations for the safe transport of hazardous chemicals

DOT: Not regulated for transport of dangerous goods.
IATA: Not regulated for transport of dangerous goods.
IMDG: Not regulated for transport of dangerous goods.

Section 15. Regulatory information

DEA: Not available
FDA: Metformin Hydrochloride Extended-Release Tablets, USP 500 mg and 1000 mg is an approved prescription medication.

Section 16. Disclaimer

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. 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.

Ajanta shall not be held liable for any damage resulting from handling or from contact with the above product.

Date: Apr 29, 2020

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