SAFETY DATA SHEETS

This SDS packet was issued with item:

078942710

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078942287 078949114 078949117

Safety Data Sheet

SECTION 1. IDENTIFICATION		
Common/Trade Name: Metronidazole Tablets USP **Chemical Name:** 1H-Imidazole-1-ethanol, 2-methyl-5-nitro- **Synonyms:** Metronidazole **Molecular Formula:** $C_6H_9N_3O_3$ **Molecular Weight:** 171.15 **CAS No:** 443-48-1 **Product Group:** Nitroimidazole.		
Manufacturer's Name	Unichem Laboratories Limited	
Address	Unichem Laboratories Limited, C-31&32, Industrial Area, Meerut Road, Ghaziabad, INDIA	
Marketed by	Unichem Pharmaceuticals (USA), Inc. Hasbrouck Heights, NJ 07604	
Phone Number	201-226-0240 (Fax : 201-368-0407)	
Emergency Phone No.	1-866-562-4616	
Recommended Use: Antibiotic agent, antiprotozoal agent.		
Restriction on Use: Prescription Only.		
SECTION 2. HAZARD(s) IDENTIFICATION		
Emergency Overview	**Physical State:** **250 mg :** White colored, round shaped, film coated, biconvex tablets with 'U' debossed on one side and '226' debossed on other side. **500 mg:** White colored, capsule shaped, film coated, biconvex tablets with 'U' debossed on one side and '227' debossed on other side. **Odor:** Not available. **WARNING!** May be harmful if swallowed. Accidental ingestion of large amounts may be harmful.	
Primary Route(s) of Entry	Ingestion	
Potential Health Effects:	**Eyes** May Cause eye irritation **Skin** Slightly hazardous in case of skin contact (irritant) **Inhalation** Not expected to be an inhalation hazard in final pharmaceutical form. **Ingestion** Ingestion of this material may cause effects similar to those seen in clinical use including dizziness, headache, diarrhea, loss of appetite, nausea or vomiting, stomach cramps, dry mouth, furry tongue, metallic taste, urinary tract discomfort and dark urine. Please see Patient Package Insert for further information	
Toxicity Data:	See Section 11	
SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS		
Composition	**CAS #**	**Quantity**
Metronidazole (active ingredient)	443-48-1	250 mg and 500 mg.
REFER to PHYSICIAN'S DESK REFERENCE for common components		
Effects of Overexposure:	Overdose may cause nausea, vomiting, trembling, weakness, numbness, tingling, pain or weakness in hands or feet, seizures and loss of coordination.	
Target Organs:	Not Found	

SECTION 4. FIRST AID MEASURES	
Eye Contact	In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.
Skin Exposure	Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
Ingestion	If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.
Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
SECTION 5. FIRE-FIGHTING MEASURES	
Flammability	Presumed to be a combustible particulate solid.
Flash Point	Not available.
Extinguishing Media	Use carbon dioxide, dry chemical, or water spray.
Special Fire Fighting Procedures	In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters. Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. Do NOT use water jet. In the event of fire and/or explosion do not breathe fumes.
Unusual Fire/Explosion Hazards	Not Applicable.
Hazardous Combustion Products	Hazardous combustion or decomposition products are expected when the product is exposed to fire.
SECTION 6. ACCIDENTAL RELEASE MEASURES	
STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES ARE SPILLED: Use appropriate personal protective equipment (see Section 8). Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained. Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.	
SECTION 7. HANDLING AND STORAGE	
Precautions **General Handling:**	Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.
Storage	Store at 20^0 to 25^0C (68^0 to 77^0F) [See USP Controlled Room Temperature].
SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION	
Engineering Controls	Apply technical measures to comply with the occupational exposure guideline. Local exhaust ventilation is needed for limited open handling or where aerosols may be generated
Respiratory Protection	Base respirator selection on a risk assessment.
Personal Protection	**Eye/face Protection** Provide eye protection based on risk assessment. **Skin Protection** Wear nitrile or latex gloves. Wear protective garment **General Hygiene Considerations** When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday. **Other** Limit access to only personnel trained in the safe handling of this material Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance
Recommended Facilities	Eye wash, washing facilities

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES					
Appearance	250 mg: White, Round biconvex 500 mg: White, Capsule shaped biconvex	Melting point	Not available	Solubility in water	Not available
Odor	odorless	Boiling point	Not available	Specific Gravity	Not available
Taste	Not available	Vapor Pressure	Not available	Flashpoint	Not available
pH	Not available	Density	Not available	Flammability Limits	Not available

SECTION 10. STABILITY AND REACTIVITY	
Stability	Stable at room temperature.
Incompatibility	None known
Hazardous Decomposition	None under normal use
Conditions to Avoid	No data available
Hazardous Polymerization	None under normal use.

SECTION 11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Metronidazole
Oral Rat : LD50 – 3 g/kg.
Oral Mouse : LD50 – 3800 mg/kg.
Other Toxicity Data : Rabbit/eye: No effect

Maximum Tolerated Dose (MTD), Oral

Metronidazole:

Carcinogenicity Several long-term studies in mice given oral doses of metronidazole at 225 mg/m^2/day or greater showed an increased incidence of pulmonary tumors and lymphomas. Doses of 500 mg/kg/day caused an increased incidence of malignant liver tumors in male mice. In several long-tem studies, statistically significant increases in various neoplasms, especially mammary and hepatic tumors, occurred in rats given metronidazole at doses greater than 285 mg/m^2/day.

Genetic Toxicity Metronidazole induced mutation in fungi and bacteria (Salmonella, E. coli) and induced prophage in bacteria. It did not induce micronuclei on bone-marrow cells of mice or rats, sister chromatid exchanges in bone marrow cells of Chinese hamsters, or unscheduled DNA synthesis in germ cells of male rabbits treated in vivo. Human cells exposed in vitro to metronidazole did not show increased incidences of chromosomal aberrations, and bonemarrow cells and lymphocytes from patients treated with metronidazole did not show increased incidences of chromosomal damage. Metronidazole did not induce sister chromatid exchanges in cultured hamster cells, sexlinked recessive lethal mutations in Drosophila, or recombination in yeast.

Reproductive Toxicity & Developmental Toxicity Retrospective studies in human administered therapeutic doses of metronidazole during pregnancy have had mixed results.
There was no increase in fetotoxicity in the offspring of mice administered oral doses of metronidazole at 20 mg/kg/day during pregnancy or in the offspring of rats administered 200 times the expected clinical dose. In mice given intraperitoneal doses of metronidazole at 15 mg/kg/day, there was a significant increase in the number of dead or malformed fetuses. No adverse effects on fertility or testicular function occurred in male rats given metronidazole in doses up to 400 mg/kg/day for 28 days, and no evidence of impaired fertility or birth defects occurred in rats given 5 times the usual human doses of metronidazole.

SECTION 12. ECOLOGICAL INFORMATION
The environmental characteristics of this formulation have not been fully evaluated. The active ingredient in this formulation may be harmful to aquatic organisms. Releases to the environment should be avoided.
SECTION 13. DISPOSAL CONSIDERATIONS
Waste Disposal Method Dispose of in accordance with local and national regulations
SECTION 14. TRANSPORT INFORMATION
The Material Safety Data Sheet (MSDS) should accompany all shipments for reference in the event of spillage or accidental release. Transportation and shipping of this product is not restricted. It has no known significant hazards requiring special packaging or labeling for air, maritime or ground transport purpose.
SECTION 15. REGULATORY INFORMATION
Suspected of damaging the unborn child. Suspected of causing cancer. DEA: Metronidazole is not a controlled substance. FDA: Metronidazole Tablets USP is an approved prescription medication.
SECTION 16. OTHER INFORMATION
ABBEVIATIONS: N/A – not applicable
Prepared by: Unichem Laboratories Limited
References: 1. Drug Bank 2. PDR – Physicians Desk Reference 3. Metronidazole Tablets USP, Package Insert, Unichem Laboratories Limited
Date: October 21, 2016 - Version: 002
SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION