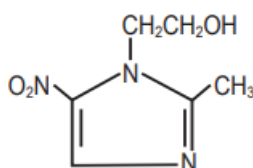


Safety Data Sheet**Metronidazole Gel USP, 0.75 %****Strength: 0.75 %****Pack Size: 45 grams,****NDC 72578-209-04****Revision No.: 00****Emergency Overview**

Metronidazole Gel USP, 0.75% contains metronidazole, USP, at a concentration of 7.5 mg per gram (0.75%) in a gel consisting of carbomer homopolymer, edetate disodium dihydrate, methyl paraben, propylene glycol, propyl paraben, purified water, and sodium hydroxide. Metronidazole is classified therapeutically as an antiprotozoal and antibacterial agent.

Section 1: Identification**Product Name: Metronidazole Gel USP, 0.75%**

Chemical Name: Chemically Metronidazole is named 2-methyl-5-nitro- 1H-imidazole-1-ethanol and has the following structure:



Description: Metronidazole gel is indicated for topical application in the treatment of inflammatory papules and pustules of rosacea.

Dosage forms and strengths: Metronidazole Gel is indicated for topical application in the treatment of inflammatory papules and pustules of rosacea. Apply and rub in a thin film of metronidazole gel twice daily, morning and evening, to entire affected areas after washing. Areas to be treated should be cleansed before application of metronidazole gel. Patients may use cosmetics after application of metronidazole gel

Manufacturer / supplier identification

Company: M/S. ZYDUS LIFESCIENCES LIMITED
Address: PLOT NOS. 254-255,
SARKHEJ-BAVLA NATIONAL HIGHWAY NO. 8A,
CHANGODAR, TAL - SANAND,
DIST. AHMEDABAD - 382210,
GUJARAT, INDIA

Contact for information: Tel.+91 2717-616430 Fax: +91 2717-616430
Emergency Telephone No: Tel.+91 2717-616401

Recommended use / Therapeutic Category: For the treatment of inflammatory papules and pustules of rosacea. / Anti protozoal and antibacterial agent.

Safety Data Sheet**Metronidazole Gel USP, 0.75 %****Strength: 0.75 %****Pack Size:** 45 grams,**NDC** 72578-209-04**Revision No.:** 00**Restriction on Use/
Contraindications**

Metronidazole gel is contraindicated in individuals with a history of hypersensitivity to metronidazole, parabens, or other ingredients of the formulation.

Section 2: Hazard (s) Identification

Dose and Administration: Apply and rub in a thin film of metronidazole gel twice daily, morning and evening, to entire affected areas after washing.
Areas to be treated should be cleansed before application of metronidazole gel. Patients may use cosmetics after application of metronidazole gel.

Adverse effects: burning, skin irritation, dryness, transient redness, metallic taste, tingling or numbness of extremities and nausea.
To report SUSPECTED ADVERSE REACTIONS, contact Viona Pharmaceuticals Inc. at 1-888-304-5011 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

| | |
|--|--|
| Physical Hazards | Not classified. |
| Health Hazards | Carcinogenicity Category 2 Specific target organ toxicity, repeated exposure Category 2 (nervous system) |
| OSHA Hazard(s) | Not classified. |
| Label Elements | |
| Signal Word | Warning |
| Hazard Statement | Suspected of causing cancer. May cause damage to organs (nervous system) through prolonged or repeated exposure. |
| Precautionary Statement | |
| Prevention | Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection. |
| Response | If exposed or concerned: Get medical advice/attention. |
| Disposal | Dispose of contents/container in accordance with local/regional/national/ international regulations. |
| Hazard(s) Not Otherwise Classified (HNOC) | Not classified. |

Section 3: Composition / information on ingredients**Active Ingredient:** Metronidazole, USP CAS#: 443-48-1**Inactive Ingredients:** Carbomer 940, edetate disodium, methylparaben, propylene glycol, propyl paraben, purified water, and sodium hydroxide.**Section 4: First -aid measures****Inhalation**

If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

Safety Data Sheet

Metronidazole Gel USP, 0.75 %

Strength: 0.75 %

Pack Size: 45 grams,

NDC 72578-209-04

Revision No.: 00

| | |
|---|---|
| Skin Contact | Rinse skin with water/shower. Get medical attention if irritation develops and persists. |
| Eye Contact | Rinse with water. Get medical attention if irritation develops and persists. |
| Ingestion | Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. |
| Most Important Symptoms/Effects, Acute and Delayed | Not available. |
| Indication of Immediate Medical Attention and Special Treatment Needed | Treatment for overdose should be symptomatic and supportive and may include the following: Administer activated charcoal as a slurry. This is most effective when administered within one hour of ingestion. Consider gastric lavage with a large-bore orogastric tube if it can be performed soon after ingestion, unless contraindicated. Control seizures prior to initiation and protect airway. For seizures: Administer intravenous benzodiazepines. Consider phenobarbital if seizures are uncontrollable or recur. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. Perform baseline CBC and renal and hepatic function tests. Metronidazole is rapidly removed by hemodialysis. Peritoneal dialysis is less effective. |
| General Information | Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. |

Section 5: Fire -fighting measures

| | |
|--|---|
| Suitable Extinguishing Media | Use fire-extinguishing media appropriate for surrounding materials. Water, foam, dry chemical or CO ₂ . |
| Unsuitable Extinguishing Media | None known. |
| Specific Hazards Arising from the Chemical | No unusual fire or explosion hazards noted. |
| Special Protective Equipment and Precautions for Firefighters | Wear suitable protective equipment. |
| Fire-Fighting Equipment/Instructions | Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing |
| Specific Methods | Use standard firefighting procedures and consider the hazards of other involved materials. |

Safety Data Sheet

Metronidazole Gel USP, 0.75 %

Strength: 0.75 %

Pack Size: 45 grams,

NDC 72578-209-04

Revision No.: 00

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures:

Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment

Methods and Materials for Containment and Cleaning Up:

Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination

Section 7: Handling and Storage

Precautions for Safe Handling

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly

Conditions for Safe Storage, Including Any Incompatibilities Storage

Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity

Store at 20° C to 25° C (68°F to 77°F); excursions permitted between 15° C to 30° C (59°F to 86°F). [see USP Controlled Room Temperature].

Keep this and all drugs out of the reach of children

Section 8: Exposure controls/personal protection

Exposure Limit Values Industrial Use

| Material | Type | Value |
|------------------------------|------|-----------------------|
| Metronidazole (CAS 443-48-1) | TWA | 0.1 mg/m ³ |

Biological Limit Values

No biological exposure limits noted for the ingredient(s). Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Appropriate Engineering Controls

Safety Data Sheet

Metronidazole Gel USP, 0.75 %

Strength: 0.75 %

Pack Size: 45 grams,

NDC 72578-209-04

Revision No.: 00

Individual Protection Measures, Such As Personal Protective Equipment

Eye/Face Protection

Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin Protection

: Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Hand Protection

For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

Other

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Respiratory Protection

Not available.

Thermal Hazards

General Hygiene Considerations

Handle in accordance with good industrial hygiene and safety practice

Section 9: Physical and chemical properties

| | |
|---|------------------------------|
| Boiling Point | 212°F |
| Physical State (liquid/solid/gas) | Gel |
| Specific Gravity (H ₂ O = 1) | Not known |
| Evaporation Rate (Ether = 1) | Same as water |
| Solubility in Water | Complete |
| Appearance | Colorless to pale yellow gel |

Section 10: Stability and reactivity

| | |
|------------------------------------|--|
| Reactivity | No reactivity hazards known. |
| Chemical Stability | Material is stable under normal conditions. |
| Possibility of Hazardous Reactions | No dangerous reaction known under conditions of normal use. |
| Conditions to Avoid | None known. |
| Incompatible Materials | Strong acids, bases, oxidizers, aluminum. |
| Hazardous Decomposition Products | NO _x . Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. |

Safety Data Sheet**Metronidazole Gel USP, 0.75 %****Strength: 0.75 %****Pack Size: 45 grams,****NDC 72578-209-04****Revision No.: 00****Section 11: Toxicological information****Information on Likely Routes of Exposure****Ingestion**

Based on available data, the classification criteria are not met.

Inhalation

Due to lack of data the classification is not possible.

Skin Contact

Due to lack of data the classification is not possible.

Eye Contact

Due to lack of data the classification is not possible.

Symptoms Related to the Physical, Chemical, and Toxicological Characteristics

dizziness, headache, trembling, weakness, numbness, pain, tingling, or weakness in hands or feet, incoordination, diarrhea, loss of appetite, nausea, vomiting, cramps, dry mouth, unpleasant taste, dark urine.

Cross Sensitivity

Persons sensitive to one nitroimidazole derivative may be sensitive to this material also.

Medical Conditions Aggravated by Exposure

Active alcoholism, epilepsy, central nervous system disorders, blood dyscrasias, candidiasis, impaired liver function.

Acute Toxicity

Based on available data, the classification criteria are not met.

| Product | species | Test Results |
|------------------------------|----------------|---------------------|
| Metronidazole (CAS 443-48-1) | Mouse | 3800 mg/kg |
| Oral LD50 | Rat | 3000 mg/kg |

Skin Corrosion/Irritation

Based on available data, the classification criteria are not met.

Serious Eye Damage/Eye Irritation

Due to lack of data the classification is not possible.

Respiratory Sensitization

Due to lack of data the classification is not possible.

Skin Sensitization

Due to lack of data the classification is not possible.

Germ Cell Mutagenicity

Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.

Mutagenicity

Bone marrow chromosomal damage in humans

Result: Negative.

Bone marrow micronucleus test in mice

Result: Negative.

Bone marrow sister chromatid exchange in Chinese hamsters

Result: Negative.

DNA synthesis in rabbits

Result: Negative.

E. coli assay

Result: Positive.

S. typhimurium Ames assay

Result: Positive

Carcinogenicity

Suspected of causing cancer. IARC: Group 2B; possibly carcinogenic to humans.

500 mg/kg/day Carcinogenicity study Result: Increased incidence of malignant liver tumors in males.

Species: Mouse

>= 225 mg/kg/day Carcinogenicity study

Result: Increased incidence of pulmonary tumors and lymphomas.

Species: Mouse

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| | |
|--------------------------------------|--|
| Ecotoxicity | No ecotoxicity data noted for the ingredient(s). |
| Persistence and Degradability | No data is available on the degradability of this product. |
| Bioaccumulative Potential | Not available. |
| Mobility in Soil | Not available. |
| Other Adverse Effects | Not available. |

Section 13: Disposal consideration

| | |
|--|--|
| Disposal Instructions | Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. |
| Local Disposal Regulations | Not available. |
| Hazardous Waste Code | Not available. |
| Waste from Residues / Unused Products | Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). |
| Contaminated Packaging | Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied. |

Section 14: Transport information

| | |
|---|---|
| DOT | Not regulated as a hazardous material by DOT. |
| IATA | Not regulated as a dangerous good. |
| Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code | No information available. |

Safety Data Sheet

Metronidazole Gel USP, 0.75 %

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Pack Size: 45 grams,

NDC 72578-209-04

Revision No.: 00

Section 15: Regulatory information

U.S. Federal Regulations:

CERCLA/SARA Hazardous Substances - Not applicable. One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard Categories

Immediate Hazard – Yes

Delayed Hazard - Yes

Fire Hazard - Yes

Pressure Hazard - No

Reactivity Hazard - No

No

No

SARA 302 Extremely Hazardous Substance

SARA 311/312 Hazardous Chemical

Other Federal Regulations

Safe Drinking Water Act (SDWA)

Not regulated.

Food and Drug Administration (FDA)

Not regulated.

U.S. State Regulations:

WARNING: This product contains a chemical known to the State of California to cause cancer.

Section 16: Other information

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.

Date of issue: 10/07/25

Supersedes edition: N/A