

Miconazole Nitrate 2% Cream
SDS Revision Date: 07/24/2026

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Section 1. IDENTIFICATION

Product Identifier used on the label

Medi ♥ First Antifungal Cream Miconazole Cream

Other means of Identification: Cartons: 55128 (1 Pk / 1. oz Tube), 55170 (4 Pk / 1 oz Tube), 55169 (6 Pk / 1 oz Tube)

Recommended use of the chemical and restrictions on use

- Over-the-counter (OTC) topical antifungal cream for the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis).

Restrictions on use:

- For external use only.
- Use only as directed on the product label.
- Avoid contact with eyes.
- Keep out of reach of children.

Chemical family:

- Topical imidazole antifungal cream

Name, address, and telephone number of the supplier (Distributor/Repackager):

Medique Products
17080 Alico Commerce Ct. Ste 1
Fort Myers, FL, USA 33967
Supplier's Telephone #: 1-800-634-7680

Name, address, and telephone number of the supplier (Manufacturer):

Galentic Pharma (India) Pvt. Ltd.
Plot No. 5-B & 5-C, Sector – III, Kandla SEZ,
Gandhidham, Gujarat – 370230, India Manufacturer's

SECTION 2: HAZARDS IDENTIFICATION

Classification of the Substance or Mixture:

- This product is **not classified as hazardous** according to the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Label Elements:

- None

Hazard Pictograms:

- None

Signal Word:

- None

Hazard Statements:

- Not classified as hazardous.

Precautionary Statements:

Prevention:

- Read and follow all label directions before use.
- Avoid contact with eyes.
- Wash hands thoroughly after handling.
- For external use only.

Response:

- If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- If irritation develops or persists, obtain medical advice.
- If swallowed, seek medical advice or contact a Poison Center.

Storage:

- Store at 15°C–30°C (59°F–86°F).
- Keep container tightly closed when not in use.
- Keep out of reach of children.

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Disposal:

- Dispose of contents / containers in accordance with local state, and federal regulations.

Hazards Not Otherwise Classified (HNOC):

- None known.

Other Information:

- This product is an over-the-counter (OTC) topical drug intended for consumer use when used according to labeled directions.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	Common Name/Synonyms	CAS Number	Concentration
Miconazole Nitrate	Miconazole Nitrate	22832-87-7	2%
Cetareth-20	Polyoxyethylene cetostearyl ether	68439-49-6	Proprietary*
Cetostearyl Alcohol	Cetearyl Alcohol	67762-27-0	Proprietary*
Chlorocresol	p-Chloro-m-cresol	59-50-7	Proprietary*
Mineral Oil	White Mineral Oil	8042-47-5	Proprietary*
Propylene Glycol	1,2-Propanediol	57-55-6	Proprietary*
Purified Water	Water	7732-18-5	Proprietary*
Petrolatum	White Petrolatum	8009-03-8	Proprietary*

*The exact concentrations of the non-hazardous excipients are withheld as trade secrets in accordance with applicable regulations.

SECTION 4: FIRST-AID MEASURES

Description of First Aid Measures:

Inhalation:

- Move the affected person to fresh air. If breathing becomes difficult or symptoms persist, seek medical attention.

Skin Contact:

- This product is intended for topical application. If irritation, redness, or an allergic reaction develops, discontinue use and wash the affected area thoroughly with soap and water. Obtain medical attention if symptoms persist.

Eye Contact:

- Immediately flush eyes with plenty of water for at least 15 minutes, lifting the upper and lower eyelids occasionally. Remove contact lenses if present and easy to do. Continue rinsing. Obtain medical attention if irritation persists.

Ingestion:

- Rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Contact a physician or Poison Center immediately if large amounts are swallowed or if symptoms develop.

Most important symptoms and effects, (acute and delayed):

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- May cause temporary eye irritation. Prolonged or repeated exposure may cause mild skin irritation or allergic skin reactions in sensitive individuals. Ingestion may result in gastrointestinal discomfort, including nausea, vomiting, or diarrhea.

Indication of immediate medical attention and special treatment needed:

- Treat symptomatically. No specific antidote is known.

SECTION 5: FIRE-FIGHTING MEASURES

Suitable extinguishing media:

- Use extinguishing media appropriate for the surrounding fire, such as water spray, dry chemical, carbon dioxide (CO₂), or alcohol-resistant foam.

Unsuitable extinguishing agent:

- None known.

Specific hazards arising from the chemical:

- This product is not expected to present unusual fire or explosion hazards. Thermal decomposition may produce irritating or toxic fumes, including oxides of carbon and nitrogen.

Special protective equipment and precautions for firefighters:

- Firefighters should wear self-contained breathing apparatus (SCBA) and full protective equipment appropriate for the surrounding fire. Use water spray to cool exposed containers.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:

- Avoid contact with eyes. Wear appropriate personal protective equipment when cleaning up large spills. Avoid creating slip hazards.

Environmental precautions:

- Prevent large quantities from entering drains, sewers, or waterways. Dispose of waste in accordance with applicable environmental regulations.

Methods and material for containment and cleaning up:

- Contain the spill if it can be done safely. Wipe up or absorb with inert absorbent material such as sand, earth, or other suitable absorbent. Place collected material into a suitable container for disposal in accordance with applicable local, state, and federal regulations. Wash the affected area with soap and water after cleanup.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:

- Use only as directed on the product label. Avoid contact with eyes, mucous membranes, and broken skin unless directed by a healthcare professional. Wash hands after handling. Keep container tightly closed when not in use. Do not contaminate food, beverages, or animal feed.

Conditions for safe storage, including any incompatibilities:

- Store at 15°C to 30°C (59°F to 86°F) in a cool, dry, well-ventilated place away from excessive heat and direct sunlight. Keep the container tightly closed when not in use. Protect from freezing. Keep out of reach of children.

Incompatible Materials:

- Strong oxidizing agents,

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters:

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Appropriate Engineering Controls:

Individual Protection Measures:

Eye/Face Protection:

Skin Protection:

Hand Protection:

Respiratory Protection:

General Hygiene Considerations:

- No occupational exposure limits have been established by OSHA, ACGIH, or NIOSH for the finished product or Hydrocortisone.
- No special engineering controls are required under normal conditions of use. Ensure adequate ventilation where large quantities are handled or processed.
- Not normally required under intended conditions of use. Safety glasses or chemical safety goggles are recommended when handling large quantities or where eye contact may occur.
- Not normally required for intended consumer use. Individuals handling large quantities should wear appropriate protective gloves if prolonged or repeated skin contact is anticipated.
- Not normally required under normal conditions of use. If ventilation is inadequate during large-scale handling or processing, use appropriate respiratory protection in accordance with applicable regulations.
- Wash hands thoroughly after handling. Avoid contact with eyes. Do not eat, drink, or smoke while handling this product.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Property	Value
Appearance	White to off-white cream
Physical State	Semi-solid (cream)
Color	White to off-white
Odor	Characteristic
Odor Threshold	Not available
pH	4.0–7.0
Melting/Freezing Point	Not available
Initial Boiling Point and Boiling Range	Not available
Flash Point	Not available
Evaporation Rate	Not available
Flammability (Solid, Gas)	Not applicable
Upper/Lower Flammability or Explosive Limits	Not available
Vapor Pressure	Not available
Vapor Density	Not available
Relative Density	Not available
Solubility	Miscible in water
Partition Coefficient (n-octanol/water)	Not available
Auto-ignition Temperature	Not available
Decomposition Temperature	Not available
Viscosity	Not available

SECTION 10: STABILITY AND REACTIVITY

Reactivity:

Chemical Stability:

Possibility of hazardous reactions:

Conditions to avoid:

Incompatible materials

- The product is not reactive under normal conditions of storage and use.
- Stable under recommended conditions.
- Hazardous polymerization will not occur.
- Excessive heat.
- Open flames and ignition sources.
- Exposure to incompatible materials.
- Strong oxidizing agents.

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Hazardous Decomposition Products:

- Thermal decomposition or combustion may produce oxides of carbon and nitrogen and other irritating or toxic fumes.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Likely Routes of Exposure:

Eye Contact:

- May cause temporary irritation, redness, or discomfort.

Skin Contact:

- Intended for topical application. Prolonged or repeated exposure may cause mild irritation or allergic skin reactions in sensitive individuals.

Inhalation:

- Inhalation is not an expected route of exposure under normal conditions of use. Airborne exposure may cause mild respiratory irritation if generated during industrial processing.

Ingestion:

- May cause gastrointestinal irritation, including nausea, vomiting, abdominal discomfort, or diarrhea if swallowed.

Symptoms Related to the Physical, Chemical, and Toxicological Characteristics:

- May cause temporary eye irritation. Sensitive individuals may experience skin irritation, redness, itching, or allergic reactions. Ingestion may result in gastrointestinal discomfort.

Delayed and Immediate Effects and Chronic Effects from Short- and Long-Term Exposure:

- No significant adverse health effects are expected when the product is used as directed. Repeated or prolonged skin exposure may result in irritation or sensitization in susceptible individuals.

Numerical Measures of Toxicity:

- No toxicity data are available for the finished product. Toxicological information for individual ingredients is available upon request.

Carcinogenicity:

- This product is not expected to present a carcinogenic hazard. None of the ingredients are listed as carcinogens by NTP, IARC, or OSHA at concentrations requiring disclosure.

Germ Cell Mutagenicity:

- Not expected to be mutagenic.

Reproductive Toxicity:

- Not expected to cause reproductive toxicity.

Specific Target Organ Toxicity (STOT):
Single Exposure:

- Not expected.

Repeated Exposure:

- Not expected

Aspiration Hazard:

- Not expected to present an aspiration hazard.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity:

- No data are available for the finished product. The product is not expected to present a significant environmental hazard when used and disposed of as directed.

Persistence and Degradability:

- No data are available for the finished product.

Bioaccumulative Potential:

- No data are available for the finished product.

Mobility in Soil:

- No data are available for the finished product.

Other Adverse Effects:

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- No known significant adverse environmental effects. Prevent large quantities from entering drains, sewers, or waterways.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal Method:

- Dispose of unused product, contaminated absorbent materials, and empty containers in accordance with applicable federal, state, and local regulations.
- Do not discharge large quantities into drains, surface waters, or sanitary sewers.

SECTION 14: TRANSPORT INFORMATION

U.S. Department of Transportation (DOT):

- Not regulated as a hazardous material

International Air Transport Association (IATA):

- Not regulated as dangerous goods.

International Maritime Dangerous Goods (IMDG)

- Not regulated as dangerous goods.

Environmental Hazards:

- Not classified as environmentally hazardous for transport.

Special Precautions for User:

- Transport in accordance with applicable regulations. Protect containers from physical damage and extreme temperatures during shipment.

Transport in Bulk (According to MARPOL 73/78 Annex II and the IBC Code):

- Not applicable

SECTION 15: REGULATORY INFORMATION

U.S. Federal Regulations:

- This product is regulated as an over-the-counter (OTC) drug by the U.S. Food and Drug Administration (FDA) and is not classified as hazardous under the OSHA Hazard Communication Standard (29 CFR 1910.1200).

TSCA Inventory:

- The components of this product are listed on, or are exempt from, the TSCA Chemical Substance Inventory.

SARA Title III (EPCRA):

Section 302 (Extremely Hazardous Substances):

- None.

Section 311/312 Hazard Categories:

- Not hazardous.

Section 313 (Toxic Chemicals):

- This product does not contain reportable quantities of substances subject to the reporting requirements of Section 313.

CERCLA (Comprehensive Environmental Response, Compensation, and Liability Act):

- This product does not contain substances regulated as hazardous under CERCLA at reportable concentrations.

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California Proposition 65:

- This product is not known to contain chemicals at levels that require warning under California Proposition 65.

Canadian Regulations:

- This product is not regulated as a hazardous product under the Workplace Hazardous Materials Information System (WHMIS), where applicable.

SECTION 16: OTHER INFORMATION (UPDATED)

Preparation Date: 1/17/2026

Reviewed Date SDS: 7/24/2026

Revision No. 2

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