Safety Data Sheet
Metronidazole Topical Cream,
Strength: 0.75 Pack Size: 45gm **NDC** 72578-129-08 **Revision No.:** 00

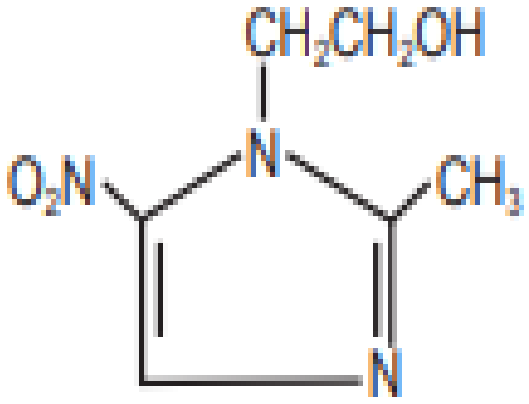
EMERGENCY OVERVIEW

Metronidazole topical cream contains metronidazole, USP, at a concentration of 7.5 mg per gram (0.75%) in an emollient cream consisting of benzyl alcohol, emulsifying wax, glycerin, isopropyl palmitate, purified water, sorbitol solution, lactic acid and sodium hydroxide to adjust pH.

Section 1. Identification

Product Name: Metronidazole Topical Cream 0.75%

Formula: $C_6H_9N_3O_3$
Chemical Name: 2-methyl-5-nitro-1H-imidazole11-ethanol.



Molecular Weight:
Description: Metronidazole topical cream contains metronidazole, USP, at a concentration of 7.5 mg per gram (0.75%) in an emollient cream consisting of benzyl alcohol, emulsifying wax, glycerin, isopropyl palmitate, purified water, sorbitol solution, lactic acid and sodium hydroxide to adjust pH.

Dosage forms and strengths: Each gram of Metronidazole Topical Cream, 0.75% contains 7.5 mg metronidazole. Areas to be treated should be washed with a mild cleanser before application. Patients may use cosmetics after application of metronidazole topical cream.

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Manufacturer / supplier identification

Company	Zydus Lifesciences Ltd. Changodar, Ahmedabad. India
Address	Plot No. 254/255, Sarkhej-Bavla, N. H 8A, Changodar. Tal. – Sanand. Dist. - Ahmedabad -382210. India.
Contact for information	Tel.:+91 2717-616430 Fax: +91 2717-616430
Emergency Telephone No	Tel.:+91 2717-616401
US customer service no.	1 (877) 993 8779

Recommended use / Therapeutic Category	Metronidazole topical cream is indicated for topical application in the treatment of inflammatory papules and pustules of rosacea
Restriction on Use / Contraindications:	Metronidazole topical cream is contraindicated in individuals with a history of hypersensitivity to metronidazole, or other ingredients of the formulation Topical metronidazole has been reported to cause tearing of the eyes. Therefore, contact with the eyes should be avoided. If a reaction suggesting local irritation occurs, patients should be directed to use the medication less frequently or discontinue use. Metronidazole is a nitroimidazole and should be used with care in patients with evidence of, or history of blood dyscrasia.

Section 2. Hazard(s) Identification

Dose and Administration	Apply and rub in a thin layer of metronidazole topical cream twice daily, morning and evening, to entire affected areas after washing. Areas to be treated should be washed with a mild cleanser before application. Patients may use cosmetics after application of metronidazole topical cream.

Adverse Effects:

In controlled clinical trials, the total incidence of adverse reactions associated with the use of metronidazole topical cream was approximately 10%. Skin discomfort (burning and stinging) was the most frequently reported event followed by erythema, skin irritation, pruritus and worsening of rosacea.
All individual events occurred in less than 3% of patients. The following additional adverse experiences have been reported with the topical use of metronidazole: dryness, transient redness, metallic taste, tingling or numbness of extremities and nausea

Over Dose Effect:

If someone has overdosed and has serious symptoms such as dryness, transient redness, metallic taste, tingling or numbness of extremities and nausea.

Ophthalmic Adverse Reactions

Metronidazole has shown evidence of carcinogenic activity in a number of studies involving chronic, oral administration in mice and rats but not in studies involving hamsters. Metronidazole has shown evidence of mutagenic activity in several in vitro bacterial assay systems. In addition, a dose-response increase in the frequency of micronuclei was observed in mice after intraperitoneal injections and an increase in chromosome aberrations have been reported in patients with Crohn's disease who were treated with 200 mg/day to 1,200 mg/day of metronidazole for 1 months to 24 months. However, no excess chromosomal aberrations in circulating human lymphocytes have been observed in patients treated for 8 months.

Pregnancy Comments

Risk Summary
Teratogenic effects There are no adequate and well-controlled studies with the use of metronidazole topical cream in pregnant women. Metronidazole crosses the placental barrier and enters the fetal circulation rapidly. No fetotoxicity was observed after oral metronidazole in rats or mice. However, because animal reproduction studies are not always predictive of human response and since oral metronidazole has been shown to be a carcinogen in some rodents, this drug should be used during pregnancy only if clearly needed.

Section 3. Composition / information on ingredients

Each gram contains:

Active: Metronidazole topical cream contains metronidazole, USP, at a concentration of 7.5 mg per gram (0.75%)

Inactive: N A

Section 4. First -aid measures

General:

Inhalation:
If respiratory irritation occurs, remove individual to fresh air.

Skin contact:
If redness, dryness or other signs of irritation occur wash the affected area with warm water and soap. If irritation persists contact a physician

Eye contact:
If redness, dryness or other signs of irritation occur wash the affected area with warm water and soap. If irritation persists contact a physician

Ingestion:
Accidental ingestion of product may necessitate medical attention. In case of accidental ingestion dilute with fluids (water or milk) and treat symptomatically. Do not induce vomiting. Never give anything by mouth to an unconscious person. Contact the nearest Poison Control Center or local emergency number. Provide an estimate of the time and amount of the substance swallowed
.

Signs and Symptoms:

Burning or stinging where the medication is applied, Skin redness or irritation, Dry, scaly, or itchy skin, Metallic taste in your mouth, Nausea, Teary & Pink eyes, Cold symptoms such as stuffy nose, sneezing, sore throat

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Overdose Treatment:

Call your doctor for medical advice about side effects/any of reaction.

Section 5. Fire -fighting measures

Suitable Extinguishing Media:	Use Dry chemical powder, Send, CO2
Unsuitable Extinguishing Media:	Water is not suitable to extinguish the fire
General fire hazards:	No unusual fire or explosion hazards noted.

Section 6. Accidental Release Measures

Personal Precautions:	Use personal protective equipment

Section 7. Handling and Storage

Precautions for Safe Handling:	Use and store according to labeled directions. Do not store in unmarked or damaged containers or storage devices. Keep containers securely closed when not in use .
Storage Conditions:	Store at 20°C to 25°C (68ºF to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].

Section 8. Exposure controls / personal protection

Respiratory Protection:	Where risk assessment shows air-purifying respirators are appropriate use a dust mask type N95 (US) or type P1 (EN 143) respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Eyes Protection:	Wear Safety glasses to avoid eye contact, moderate irritation may result. May cause irritation in some sensitive individuals.

Section 9. Physical and chemical properties

Appearance:	White.
Solubility:	Partially soluble
Melting Point:	NA

Section 10. Stability and Reactivity

Reactive with :	This product is Stable. Avoid to store with Strong acids/bases.
Chemical Stability:	Stable Under recommended storage conditions.

Section 11. Toxicological information

Information on the Likely Routes of Exposure:

General Information. Oral or topical contact with high concentrations of one or more of the components in this formulation may produce hypersensitivity in a small number of the general population. As the concentration of these components is relatively small in the finished product, this formulation should not present significant contact hazards to humans.

- **Ingestion:** Harmful if inhaled & may cause respiratory tract irritation.
- **Skin Contact:** Skin redness or irritation.
- **Eye Contact:** Teary eyes and pink eyes
- **Carcinogenicity:** Carcinogenesis, mutagenesis, impairment of fertility.

Section 12. Ecological information

Do not allow product to enter drinking water supplies, waste water or soil.

Section 13. Disposal Consideration

Product Observe all federal, state, and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.
Contaminated packaging Dispose of as unused product.

Section 14. Transport Information

ADR/RID
Not dangerous goods
IMDG
Not dangerous goods
IATA
Not dangerous goods

Section 15. Regulatory Information

Hazard symbols
Xn Harmful
R-phrase(s) R40 Limited evidence of a carcinogenic effect.
S-phrase(s) S36/37 Wear suitable protective clothing and gloves

Section 16. Other information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product.

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Date of issue: 08/08/23 **Supersedes edition: NA**

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