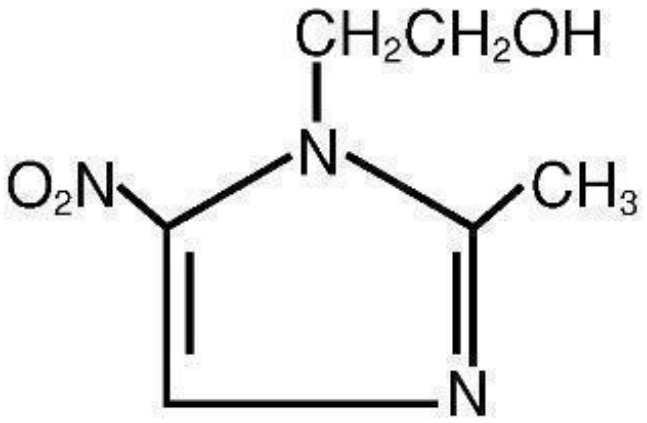
METRONIDAZOLE- metronidazole cream
Mayne Pharma Inc.

Metronidazole
Topical Cream, 0.75%

Rx only
FOR TOPICAL USE ONLY
(NOT FOR OPHTHALMIC USE)

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/or sodium hydroxide to adjust pH. Metronidazole is a member of the imidazole class of antibacterial agents and is classified therapeutically as an antiprotozoal and antibacterial agent. Chemically, metronidazole is 2-methyl-5-nitro-1*H*- imidazole-1-ethanol. The molecular formula is $C_6H_9N_3O_3$ and molecular weight is 171.16. Metronidazole is represented by the following structural formula:



CLINICAL PHARMACOLOGY:

The mechanisms by which metronidazole acts in the treatment of rosacea are unknown, but appear to include an anti-inflammatory effect.

INDICATIONS AND USAGE:

Metronidazole Topical Cream is indicated for topical application in the treatment of inflammatory papules and pustules of rosacea.

CONTRAINDICATIONS:

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

PRECAUTIONS:

General:

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.

Information for patients:

This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.

Drug Interactions:

Oral metronidazole has been reported to potentiate the anticoagulant effect of warfarin and coumarin anticoagulants, resulting in a prolongation of prothrombin time. The effect of topical metronidazole on prothrombin time is not known.

Carcinogenesis, mutagenesis, impairment of fertility:

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 200-1200 mg/day of metronidazole for 1 to 24 months. However, no excess chromosomal aberrations in circulating human lymphocytes have been observed in patients treated for 8 months.

Pregnancy:

Teratogenic effects: Pregnancy category B: 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.

Nursing mothers:

After oral administration, metronidazole is secreted in breast milk in concentrations similar to those found in the plasma. Even though blood levels are significantly lower with

topically applied metronidazole than those achieved after oral administration of metronidazole, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric use:

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS:

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.

DOSAGE 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.

HOW SUPPLIED:

Metronidazole Topical Cream, 0.75% is supplied in a 45 g aluminum tube -**NDC** 68308**-711-**45**.**

Storage conditions: STORE AT CONTROLLED ROOM TEMPERATURE, 68° TO 77°F (20° TO 25°C), EXCURSIONS PERMITTED BETWEEN 59° AND 86°F (15° TO 30°C).

DIstributed by:
Mayne Pharma
Raleigh, NC 27609
1-844-825-8500

Product of Canada

P58249-0
Revised: 10/2024

Package Label

NDC 68308-**711**-45

Metronidazole Topical Cream
0.75%

Rx Only
Net Wt. 45 g

maynepharma

Product of Canada

Distributed by:
Mayne Pharma
Raleigh, NC 27609

Rev. 10/2024
P58248-0

FOR TOPICAL USE ONLY. NOT FOR OPHTHALMIC USE.

STORE AT CONTROLLED ROOM TEMPERATURE, 68° TO 77°F (20° TO 25°C), EXCURSIONS PERMITTED BETWEEN 59° AND 86°F (15° TO 30°C).

Usual dosage: Apply a thin layer to entire affected areas after washing. Use morning and evening or as directed by physician. Avoid application close to the eyes.

Each gram contains: Active: metronidazole 0.75% (7.5 mg).

Inactive: benzyl alcohol, emulsifying wax, glycerin, isopropyl palmitate, purified water, sorbitol solution, lactic acid and/or sodium hydroxide to adjust pH.

See crimp end for lot number and expiration date.

METRONIDAZOLE

metronidazole cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68308-711
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
METRONIDAZOLE (UNII: 140QMO216E) (METRONIDAZOLE - UNII:140QMO216E)	METRONIDAZOLE	7.5 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
BENZYL ALCOHOL (UNII: LKG8494WBH)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
LACTIC ACID (UNII: 33X04XA5AT)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68308-711-45	1 in 1 CARTON	05/19/2025	
1		45 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA020531	05/19/2025	

Labeler - Mayne Pharma Inc. (867220261)

Establishment

Name	Address	ID/FEI	Business Operations
G Production Inc.		251676961	manufacture(68308-711)

Revised: 10/2024 Mayne Pharma Inc.