

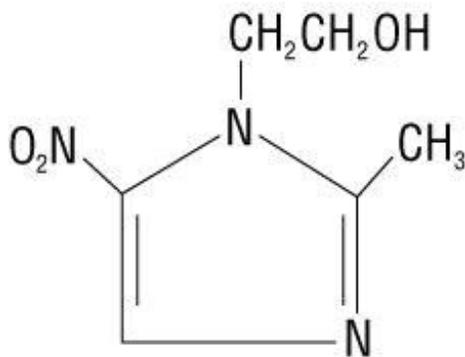
METRONIDAZOLE- metronidazole gel

Viona Pharmaceuticals Inc

Metronidazole Gel USP, 0.75%

DESCRIPTION

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, methylparaben, propylene glycol, propylparaben, purified water, and sodium hydroxide. Metronidazole is classified therapeutically as an antiprotozoal and antibacterial agent. Chemically, metronidazole is named 2-methyl-5-nitro-1*H*-imidazole-1-ethanol and has the following structure:



CLINICAL PHARMACOLOGY

Bioavailability studies on the topical administration of 1 gram of metronidazole Gel (7.5 mg of metronidazole) to the face of 10 rosacea patients showed a maximum serum concentration of 66 nanograms per milliliter in one patient. This concentration is approximately 100 times less than concentrations afforded by a single 250 mg oral tablet. The serum metronidazole concentrations were below the detectable limits of the assay at the majority of time points in all patients. Three of the patients had no detectable serum concentrations of metronidazole at any time point. The mean dose of gel applied during clinical studies was 600 mg which represents 4.5 mg of metronidazole per application. Therefore, under normal usage levels, the formulation affords minimal serum concentrations of metronidazole. The mechanisms by which metronidazole gel acts in the treatment of rosacea are unknown, but appear to include an antiinflammatory effect.

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

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

PRECAUTIONS

General: Metronidazole Gel 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 coumarin and warfarin 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 mg/day to 1,200 mg/day of metronidazole for 1 month to 24 months. However, no excess chromosomal aberrations in circulating human lymphocytes have been observed in patients treated for 8 months.

Pregnancy: *Teratogenic effects:*

There has been no experience to date with the use of metronidazole gel in pregnant patients. 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 metronidazole gel blood levels are significantly lower than those achieved after oral 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

The following adverse experiences have been reported with the topical use of metronidazole: 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.

DOSAGE 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.

HOW SUPPLIED

Metronidazole Gel USP, 0.75% is supplied in a 45 g tube

NDC 72578-209-04

Storage conditions:

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.

Manufactured by:

Zydus Lifesciences Ltd.

Changodar, Ahmedabad-382210, India

Distributed by:

Viona Pharmaceuticals Inc.

Cranford, NJ 07016

Rev: 12/24

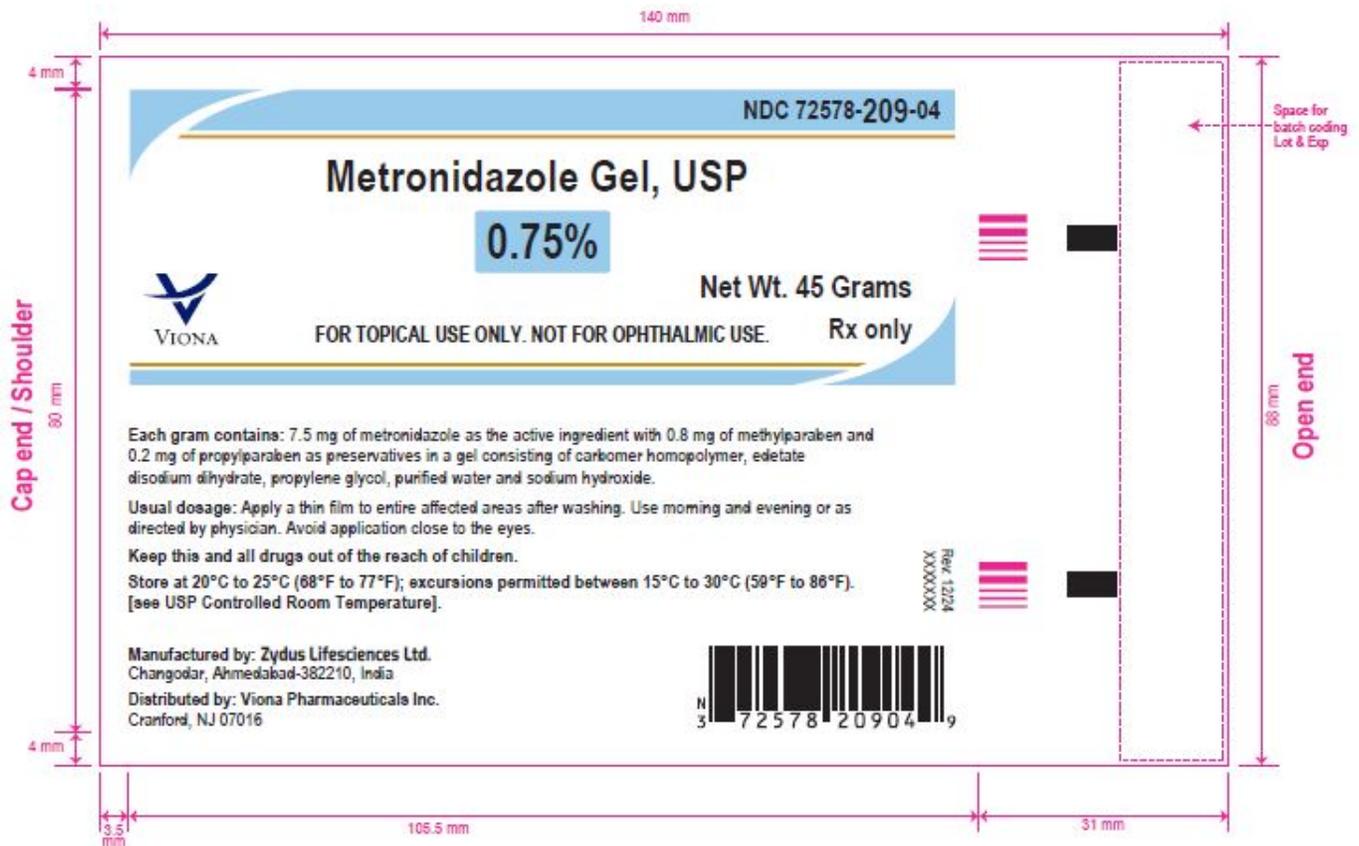
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 72578-209-04

Metronidazole Gel USP, 0.75%

45 grams

Rx



Metronidazole Gel, USP

METRONIDAZOLE

metronidazole gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72578-209
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
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72578-209-04	1 in 1 CARTON	02/14/2026	
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
ANDA	ANDA220095	02/14/2026	

Labeler - Viona Pharmaceuticals Inc (081468959)

Registrant - Zydus Lifesciences Limited (650199482)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		650650802	ANALYSIS(72578-209) , MANUFACTURE(72578-209)

Revised: 2/2026

Viona Pharmaceuticals Inc