

**ROSADAN- metronidazole gel**  
**ROSADAN- metronidazole**  
**Medimetriks Pharmaceuticals, Inc.**

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**Rosadan® GEL**  
**Metronidazole Gel USP, 0.75%**

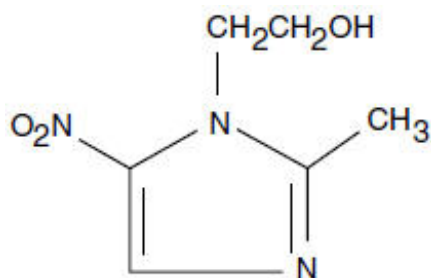
FOR TOPICAL USE ONLY (NOT FOR OPHTHALMIC USE)

**Rx Only**

**DESCRIPTION**

Rosadan® (metronidazole) Gel contains metronidazole, USP, at a concentration of 7.5 mg per gram (0.75%) in a gel consisting of carbomer homopolymer NF, edetate disodium, 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 Rosadan® (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 Rosadan® (metronidazole) Gel acts in the treatment of rosacea are unknown, but appear to include an anti-inflammatory effect.

**INDICATIONS AND USAGE**

Rosadan® (metronidazole) Gel is indicated for topical application in the treatment of inflammatory papules and pustules of rosacea.

**CONTRAINDICATIONS**

Rosadan® (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 200-1200 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 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 Medimetriks Pharmaceuticals, Inc. at 1-973-882-7512 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

## **DOSAGE AND ADMINISTRATION**

Apply and rub in a thin film of Rosadan<sup>®</sup> (metronidazole) Gel twice daily, morning and evening, to entire affected areas after washing.

Areas to be treated should be cleansed before application of Rosadan<sup>®</sup> (metronidazole) Gel. Patients may use cosmetics after application of Rosadan<sup>®</sup> (metronidazole) Gel.

## **HOW SUPPLIED**

Rosadan<sup>®</sup> (metronidazole) Gel USP, 0.75% is supplied in a 45 g tube NDC 43538-182-45

## **Storage conditions**

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

Manufactured for:

**MEDIMETRIKS  
PHARMACEUTICALS, INC.**

383 Route 46 West  
Fairfield, NJ 07004-2402  
[www.medimetriks.com](http://www.medimetriks.com)

Manufactured by:

G&W Laboratories, Inc.  
South Plainfield, NJ 07080

8-0637BFMDMLNC2  
Rev. 08/2019  
GW 7313  
IP024-R4

## **PRINCIPAL DISPLAY PANEL - 45 g Tube Carton**

MEDIMETRIKS  
PHARMACEUTICALS, INC.

NDC 43538-182-45

R<sub>x</sub> Only

Rosadan<sup>®</sup> GEL  
Metronidazole Gel USP, 0.75%

NET WT 45 g



## PRINCIPAL DISPLAY PANEL - Kit Carton

NDC 43538-183-45

*Rx Only*

**Rosadan<sup>®</sup>**

**Metronidazole Gel USP, 0.75%**

**GEL KIT**

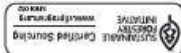
### CONTENTS:

- 1- Rosadan<sup>®</sup>  
Metronidazole Gel USP,  
0.75% Tube (Net wt. 45 g)
- 1- Rehyla<sup>®</sup> Wash  
Moisturizing Daily Wash  
Bottle (16 fl. oz.)

**MEDIMETRIKS  
PHARMACEUTICALS, INC.**



Expiration Date Imprint, Lot # and  
Serialization code, Lot # and



IC120-R1

Manufactured for: Medimetrix Pharmaceuticals, Inc.  
383 Route 46 West, Fairfield, NJ 07004 • 973-882-7512  
Made in USA

**Rx Only**  
**Rosadan® GEL**  
Metronidazole Gel USP, 0.75%

Manufactured for: Medimetrix Pharmaceuticals, Inc.  
383 Route 46 West, Fairfield, NJ 07004 • 973-882-7512  
Made in USA

**REHYLA® WASH**

NDC 43538-183-45

**CONTENTS:**  
1- Rosadan®  
Metronidazole Gel USP  
0.75% Tube (Net wt. 45 g)  
1- Rehyla® Wash  
Moisturizing Daily Wash  
Bottle (16 fl. oz.)



**Rx Only**  
**Rosadan®**  
Metronidazole Gel USP, 0.75%  
**GEL KIT**

NDC 43538-183-45

NDC 43538-183-45

**Rx Only**  
**Rosadan®**  
Metronidazole Gel USP, 0.75%

**GEL KIT**

**CONTENTS:**  
1- Rosadan®  
Metronidazole Gel USP,  
0.75% Tube (Net wt. 45 g)  
1- Rehyla® Wash  
Moisturizing Daily Wash  
Bottle (16 fl. oz.)



NDC 43538-183-45

**Rx Only**  
**Rosadan**

# Rosadan® Metronidazole Gel USP, 0.75%

## GEL KIT

### CONTENTS:

- 1- Rosadan®  
Metronidazole Gel USP,  
0.75% Tube (Net wt. 45 g)
- 1- Rehya® Wash  
Moisturizing Daily Wash  
Bottle (1.6 fl. oz.)



*Medimetrics Pharmaceuticals guarantees that this product was manufactured with the highest pharmaceutical control standards, the most desirable ingredients, under strict demands for quality and safety, ensuring batch-to-batch quality and use-to-use consistency.*

**Metronidazole Gel USP, 0.75%**

**DOSE AND ADMINISTRATION:** Apply a thin film of Rosadan® (metronidazole) Gel to entire affected areas after washing. Use morning and evening, or as directed by physician.

Areas to be treated should be washed with a mild cleanser before application. Patients may use cosmetics after application of Rosadan® (metronidazole) Gel.

**For topical use only. Not for ophthalmic use.**

Store at 20°-25°C (68°-77°F)  
[see USP Controlled Room Temperature].

For lot and expiration date, see end of carton.

**WASH**

Rehya® Wash is a mild cleanser that can be used daily to deeply clean and moisturize sensitive skin.

**DIRECTIONS:** Wet skin and pump Rehya® Wash into hands. Massage gently into skin. Rinse thoroughly and pat dry with a soft towel. For best results, use twice daily.

Caution: For external use only. Avoid contact with eyes, lips and mucous membranes. If contact occurs, rinse well with water. If rash or irritation develops, discontinue use. Keep out of reach of children.

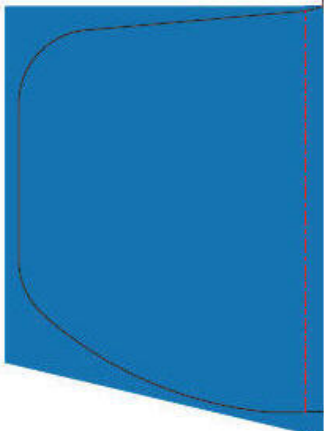
**STORAGE:** Store at 15°C-30°C (59°F-86°F).

For lot number, see bottom of carton.



Rosadan<sup>®</sup> Rx Only  
GEL

REHYLA<sup>®</sup>



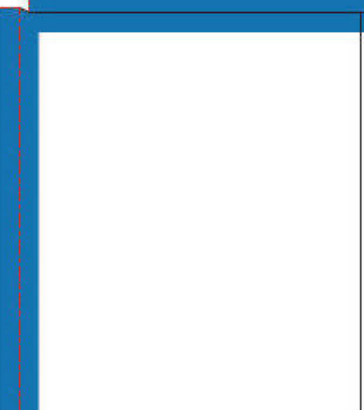
NDC 43538-183-45

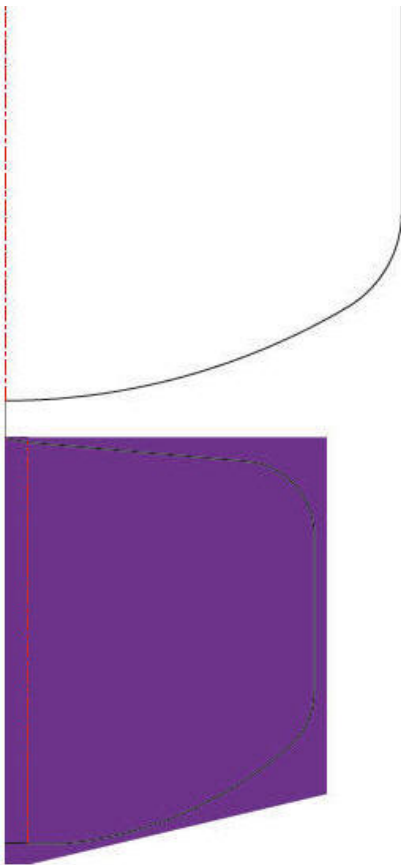
MEDIMETRICS  
PHARMACEUTICALS, INC.

Rx Only  
**Rosadan<sup>®</sup>**  
Metronidazole Gel USP, 0.75%  
**GEL KIT**

**CONTENTS:**

- 1 - Rosadan<sup>®</sup> Metronidazole Gel USP, 0.75% Tube (Net wt. 4.5 g)
- 1 - Rehyla<sup>®</sup> Wash Moisturizing Daily Wash Bottle (1.6 fl. oz.)





## ROSADAN

metronidazole gel

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:43538-182
<b>Route of Administration</b>	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
edetate disodium (UNII: 7FLD91C86K)	
methylparaben (UNII: A2I8C7HI9T)	
propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
sodium hydroxide (UNII: 55X04QC32I)	

### Product Characteristics



<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43538-182-45	1 in 1 CARTON	04/15/2012	
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	ANDA078178	04/15/2012	

## ROSADAN

metronidazole kit

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:43538-183
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43538-183-45	1 in 1 CARTON; Type 0: Not a Combination Product	08/01/2011	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	45 g
Part 2	1 BOTTLE, PUMP	454 g

## Part 1 of 2

## ROSADAN

metronidazole gel

### Product Information

<b>Route of Administration</b>	TOPICAL
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### 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
edetate disodium (UNII: 7FLD91C86K)	
methylparaben (UNII: A2I8C7HI9T)	
propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
sodium hydroxide (UNII: 55X04QC32I)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
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	ANDA078178	04/15/2012	

## Part 2 of 2

### REHYLA WASH

cleansing (cold creams, cleansing lotions, liquids, and pads)

### Product Information

Route of Administration	TOPICAL
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### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	water (UNII: 059QF0KO0R)	
INGR	glyceryl monostearate (UNII: 230OU9XXE4)	
INGR	glycerin (UNII: PDC6A3C0OX)	
INGR	cetyl alcohol (UNII: 936JST6JCN)	
INGR	disodium oleamido mipa-sulfosuccinate (UNII: 0MBZ20845F)	
INGR	cholesterol (UNII: 97C5T2UQ7J)	
INGR	disodium laureth sulfosuccinate (UNII: D6DH1DTN7E)	
INGR	caprylyl glycol (UNII: 00YIU5438U)	
INGR	propylene glycol (UNII: 6DC9Q167V3)	
INGR	phenoxyethanol (UNII: HIE492ZZ3T)	

INGR	<b>sodium cocoyl isethionate</b> (UNII: 518XTE8493)	
INGR	<b>cocamidopropyl betaine</b> (UNII: 5OCF3O11KX)	
INGR	<b>sodium methyl cocoyl taurate</b> (UNII: JVL98CG53G)	
INGR	<b>C13-14 isoparaffin</b> (UNII: E4F12ROE70)	
INGR	<b>sodium chloride</b> (UNII: 451W47IQ8X)	
INGR	<b>niacinamide</b> (UNII: 25X51I8RD4)	
INGR	<b>edetate disodium</b> (UNII: 7FLD91C86K)	
INGR	<b>hexylene glycol</b> (UNII: KEH0A3F75J)	
INGR	<b>laureth-7</b> (UNII: Z95S6G8201)	
INGR	<b>chamaemelum nobile flower</b> (UNII: O2T154T6OG)	
INGR	<b>hyaluronate sodium</b> (UNII: YSE9PPT4TH)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		454 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		08/01/2011	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078178	08/01/2011	

**Labeler** - Medimetriks Pharmaceuticals, Inc. (01903816)

### Establishment

Name	Address	ID/FEI	Business Operations
Cosette Pharmaceuticals, Inc.		1169 18230	MANUFACTURE(43538-182, 43538-183)

Revised: 11/2019

Medimetriks Pharmaceuticals, Inc.