

**MONISTAT-DERM- miconazole nitrate cream**  
**Ortho Dermatological**

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**MONISTAT-DERM**  
**(miconazole nitrate 2%)**  
**Cream**

**For Topical Use Only**

**Description:**

MONISTAT-DERM (miconazole nitrate 2%) Cream contains miconazole nitrate\* 2%, formulated into a water-miscible base consisting of pegoxol 7 stearate, peglicol 5 oleate, mineral oil, benzoic acid, butylated hydroxyanisole and purified water.

\*Chemical name: 1-[2,4-dichloro-B-{(2,5-dichlorobenzyl) oxy} phenethyl] imidazole mononitrate.

**Actions:**

Miconazole nitrate is a synthetic antifungal agent which inhibits the growth of the common dermatophytes, *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum*, the yeast-like fungus, *Candida albicans*, and the organism responsible for tinea versicolor (*Malassezia furfur*).

**Indications:**

For topical application in the treatment of tinea pedis (athlete's foot), tinea cruris, and tinea corporis caused by *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum*, in the treatment of cutaneous candidiasis (moniliasis), and in the treatment of tinea versicolor.

**Contraindications:**

MONISTAT-DERM (miconazole nitrate 2%) Cream has no known contraindications.

**Precautions:**

If a reaction suggesting sensitivity or chemical irritation should occur, use of the medication should be discontinued.

For external use only. Avoid introduction of MONISTAT-DERM Cream into the eyes.

**Adverse Reactions:**

There have been isolated reports of irritation, burning, maceration, and allergic contact dermatitis associated with the application of MONISTAT-DERM.

**Dosage and Administration:**

Sufficient MONISTAT-DERM Cream should be applied to cover affected areas twice daily (morning and evening) in patients with tinea pedis, tinea cruris, tinea corporis, and cutaneous candidiasis, and once daily in patients with tinea versicolor. If MONISTAT-DERM Cream is used in intertriginous areas, it should be applied sparingly and smoothed in well to avoid maceration effects.

Early relief of symptoms (2 to 3 days) is experienced by the majority of patients and clinical

improvement may be seen fairly soon after treatment is begun; however, *Candida* infections and tinea cruris and corporis should be treated for two weeks and tinea pedis for one month in order to reduce the possibility of recurrence. If a patient shows no clinical improvement after a month of treatment, the diagnosis should be redetermined. Patients with tinea versicolor usually exhibit clinical and mycological clearing after two weeks of treatment.

### How Supplied:

MONISTAT-DERM (miconazole nitrate 2%) Cream containing miconazole nitrate at 2% strength is supplied in 15g, 1 oz. and 3 oz. tubes.

Ortho Dermatological  
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 Pharmaceutical, Inc.  
 Skillman, New Jersey 08558

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<b>MONISTAT-DERM</b>				
miconazole nitrate cream				
<b>Product Information</b>				
<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0062-5434	
<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	Miconazole nitrate (UNII: VW4H1CYW1K) (Miconazole nitrate - UNII:VW4H1CYW1K)		20 mg in 1 g	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>	<b>Strength</b>		
	Pegoxol 7 stearate ()			
	Peglicol 5 oleate ()			
	Mineral oil ()			
	Benzioc acid ()			
	Butylated hydroxyanisole ()			
	Water (UNII: 059QF0KO0R)			
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0062-5434-02	15 g in 1 TUBE		
2	NDC:0062-5434-01	28 g in 1 TUBE		
3	NDC:0062-5434-03	85 g in 1 TUBE		

**Labeler** - Ortho Dermatological

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