

**MICONAZOLE NITRATE 1%- miconazole spray**  
**Butler Animal health Supply, LLC dba Covetrus North America**

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**Miconazole  
nitrate 1%**

**Lotion/Spray**

Topical antifungal agent for dogs and cats

**CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.**

**Not for Use in Humans**  
**Keep Out of Reach of Children**

Approved by FDA under ANADA # 200-362

Miconazole nitrate 1% Lotion is available in 60 mL bottles with droppers.

Miconazole nitrate 1% Spray is available in 120 mL and 240 mL bottles with spray mister.

**Indications:**

For the treatment of fungal infections in dogs and cats caused by *Microsporum canis*, *Microsporum gypseum*, and *Trichophyton mentagrophytes*.

**Dosage:**

Apply a light covering to affected areas, once daily for 2 to 4 weeks. See accompanying literature for full directions.

Avoid contact with eyes, since irritation may result.

Wash hands thoroughly after administration to avoid spread of fungal infection.



Lot No. / Exp. Date

**Active ingredient:**

Miconazole nitrate . . . . . 1.15%  
(equivalent to 1% miconazole base by weight)

**Storage:**

Store at controlled room temperature between 15° to 30°C (59°-86°F).  
Keep container tightly closed when not in use.

**Reorder #014676** 60 mL AH-014676-L-04 REV: 0723

**Reorder #014677** 120 mL AH-014677-L-04 REV: 0723

**Reorder #014678** 240 mL AH-014678-L-03 REV: 0323

**Questions?** (855) 724-3461

Distributed by:  
Covetrus® North America  
400 Metro Place North  
Dublin, OH 43017  
**covetrus.com**

### **Description:**

Miconazole nitrate 1% Spray is a synthetic antifungal agent for use in dogs and cats. It contains: 1.15% miconazole nitrate (equivalent to 1% miconazole base by weight), polyethylene glycol 400, and ethyl alcohol 55%.

### **Precautions:**

In the event of sensitization or irritation due to Miconazole nitrate 1% Spray, treatment should be discontinued. Avoid contact with eyes, since irritation may result. Wash hands thoroughly after administration to avoid spread of fungal infection.

### **Dosage and administration:**

Accurate diagnosis of the infecting organism is essential. Identification should be made either by direct microscopic examination of a mounting of infected tissue in a solution of potassium hydroxide, or by culture on an appropriate medium.

### **Spray:**

Spray affected areas from a distance of 2 to 4 inches to apply a light covering, once daily for 2 to 4 weeks. Do not allow pet to contact finished wood surfaces until pet is thoroughly dried.

Medication must be continued until the infecting organism is completely eradicated as indicated by appropriate clinical or laboratory examination. If no improvement is noticed within 2 weeks, diagnosis should be re-evaluated. Difficult cases may require treatment for 6 weeks.

General measures in regard to hygiene should be observed to control sources of infection or reinfection. Clipping of hair around and over the sites of infection should be done at the start of treatment and again as necessary.

### **Lotion:**

Apply a light covering of Miconazole nitrate 1% Lotion to affected areas, once daily, for 2 to 4 weeks. Application is best accomplished using a gauze pad or cotton swab.

Medication must be continued until the infecting organism is completely eradicated as indicated by appropriate clinical or laboratory examination. If no improvement is noticed within 2 weeks, diagnosis should be re-evaluated. Difficult cases may require treatment for 6 weeks.

General measures in regard to hygiene should be observed to control sources of infection or reinfection. Clipping of hair around and over the sites of infection should be done at the start of treatment and again as necessary.

## CONTACT INFORMATION:

To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Covetrus® at (855) 724-3461 or covetrus.com. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>

**60 mL**

**covetrus** 

**OPEN HERE** 

**Indications:** For the treatment of fungal infections in dogs and cats caused by *Microsporum canis*, *Microsporum gypseum*, and *Trichophyton mentagrophytes*.

**Dosage:** Apply a light covering to affected areas, once daily for 2 to 4 weeks. See accompanying literature for full directions.

Avoid contact with eyes, since irritation may result.

Wash hands thoroughly after administration to avoid spread of fungal infection.

 **OVERSEAS LABEL**  
INSTRUCTIONS

Lot No. / Exp. Date

**NO VARNISH**

NDC: 11695-2221-2

**Miconazole nitrate 1% Lotion**

Topical Antifungal Agent For Dogs and Cats

**CAUTION:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**Not for Use in Humans**  
**Keep Out of Reach of Children**

Approved by FDA under ANADA # 200-362  
2 fl oz (60 mL)

**Active ingredient:**  
Miconazole nitrate ..... 1.15%  
(equivalent to 1% miconazole base by weight)

**Storage:** Store at controlled room temperature between 15° to 30°C (59°-86°F). Keep container tightly closed when not in use.

**Reorder #014676**  
**Questions? (855) 724-3461**

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AH-014676-L-04  
REV: 0723

  
40066 50113

## Miconazole nitrate 1% Lotion

Topical antifungal agent for dogs and cats.

**Description:** Miconazole nitrate 1% Lotion is a synthetic antifungal agent for use in dogs and cats. It contains: 1.15% miconazole nitrate (equivalent to 1% miconazole base by weight), polyethylene glycol 400, and ethyl alcohol 55%.

**Indications:** Miconazole nitrate 1% Lotion is indicated for the treatment of fungal infections in dogs and cats caused by *Microsporum canis*, *Microsporum gypseum*, and *Trichophyton mentagrophytes*.

**Precautions:** In the event of sensitization or irritation due to Miconazole nitrate 1% Lotion, treatment should be discontinued. Avoid contact with eyes, since irritation may result. Wash hands thoroughly after administration to avoid spread of fungal infection.

**Dosage and administration:** Accurate diagnosis of the infecting organism is essential. Identification should be made either by direct microscopic examination of a mounting of infected tissue in a solution of potassium hydroxide, or by culture on an appropriate medium.

**Lotion:** Apply a light covering of Miconazole nitrate 1% Lotion to affected areas, once daily, for 2 to 4 weeks. Application is best accomplished using a gauze pad or cotton swab.

Medication must be continued until the infecting organism is completely eradicated as indicated by appropriate clinical or laboratory examination. If no improvement is noticed within 2 weeks, diagnosis should be re-evaluated. Difficult cases may require treatment for 6 weeks.

General measures in regard to hygiene should be observed to control sources of infection or reinfection. Clipping of hair around and over the sites of infection should be done at the start of treatment and again as necessary.

**How supplied:** Miconazole nitrate 1% Lotion is available in 60 mL bottles with droppers.

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**CONTACT INFORMATION:** To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Covetrus® at (855) 724-3461 or covetrus.com. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>

REV: 0723

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Approved by FDA  
under ANADA # 200-362





**Miconazole nitrate 1% Lotion 2 fl oz (60 mL)**  
**Not for Use in Humans - Keep Out of Reach of Children**

Quantity: 12 bottles

Approved by FDA under ANADA # 200-362

Reorder #014676

Questions?

(855) 724-3461

Distributed by:

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400 Metro Place North

Dublin, OH 43017

[covetrus.com](http://covetrus.com)

ITEM NUMBER



(01) 10840066501137

EXP. DATE



YYYY/MMM

LOT NUMBER



XXXX

QUANTITY



XX

Made in U.S.A.

AH-014676-C-02

REV: 0723



**Miconazole nitrate 1% Lotion 2 fl oz (60 mL)**

**Not for Use in Humans**

**Keep Out of Reach of Children**

Quantity: 72 bottles (6 inner cases x 12 bottles)

Approved by FDA under ANADA # 200-362

Reorder #014676

Questions?

(855) 724-3461

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ITEM NUMBER



(01) 20840066501134

EXP. DATE



YYYY/MMM

LOT NUMBER



XXXX

CASE QUANTITY



XX

Made in U.S.A.

AH-014676-S-02

REV: 0723

120 mL



**Indications:** For the treatment of fungal infections in dogs and cats caused by *Microsporum canis*, *Microsporum gypseum*, and *Trichophyton mentagrophytes*.

**Dosage:** Apply a light covering to affected areas, once daily for 2 to 4 weeks. See accompanying literature for full directions.

Avoid contact with eyes, since irritation may result.

Wash hands thoroughly after administration to avoid spread of fungal infection.



Lot No. / Exp. Date

**NO VARNISH**

NDC: 11695-2221-4

# Miconazole nitrate 1% Spray

Topical antifungal agent for dogs and cats

**CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.**

**Not for Use in Humans  
Keep Out of Reach of Children**

Approved by FDA  
under ANADA # 200-362

4 fl oz (120 mL)

**Active ingredient:**

Miconazole nitrate ..... 1.15%  
(equivalent to 1% miconazole base by weight)

**Storage:** Store at controlled room temperature between 15° to 30°C (59°-86°F). Keep container tightly closed when not in use.

Reorder #014677

Questions? (855) 724-3461

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AH-014677-L-04  
REV: 0723

# Miconazole nitrate 1% Spray

Topical antifungal agent for dogs and cats.

**Description:** Miconazole nitrate 1% Spray is a synthetic antifungal agent for use in dogs and cats. It contains: 1.15% miconazole nitrate (equivalent to 1% miconazole base by weight), polyethylene glycol 400, and ethyl alcohol 55%.

**Indications:** Miconazole nitrate 1% Spray is indicated for the treatment of fungal infections in dogs and cats caused by *Microsporum canis*, *Microsporum gypseum*, and *Trichophyton mentagrophytes*.

**Precautions:** In the event of sensitization or irritation due to Miconazole nitrate 1% Spray, treatment should be discontinued. Avoid contact with eyes, since irritation may result. Wash hands thoroughly after administration to avoid spread of fungal infection.

**Dosage and administration:** Accurate diagnosis of the infecting organism is essential. Identification should be made either by direct microscopic examination of a mounting of infected tissue in a solution of potassium hydroxide, or by culture on an appropriate medium.

**Spray:** Spray affected areas from a distance of 2 to 4 inches to apply a light covering, once daily for 2 to 4 weeks. Do not allow pet to contact finished wood surfaces until pet is thoroughly dried.

Medication must be continued until the infecting organism is completely eradicated as indicated by appropriate clinical or laboratory examination. If no improvement is noticed within 2 weeks, diagnosis should be re-evaluated. Difficult cases may require treatment for 6 weeks.

General measures in regard to hygiene should be observed to control sources of infection or reinfection. Clipping of hair around and over the sites of infection should be done at the start of treatment and again as necessary.

**How supplied:** Miconazole nitrate 1% Spray is available in 120 mL and 240 mL bottles with spray misters.

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**CONTACT INFORMATION:** To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Covetrus® at (855) 724-3461 or [covetrus.com](http://covetrus.com). For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>

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REV: 0723



Approved by FDA  
under ANADA # 200-362



# Miconazole nitrate 1% Spray 4 fl oz (120 mL)

Not for Use in Humans - Keep Out of Reach of Children

Quantity: 12 bottles

Approved by FDA under ANADA # 200-362

Reorder #014677

Questions?

(855) 724-3461

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400 Metro Place North

Dublin, OH 43017

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ITEM NUMBER



(01) 10840066501144

EXP. DATE



YYYY/MMM

LOT NUMBER



XXXX

QTY



XX

Made in U.S.A.

AH-014677-C-02

REV: 0723



# Miconazole nitrate 1% Spray 4 fl oz (120 mL)

Not for Use in Humans

Keep Out of Reach of Children

Quantity: 12 bottles (1 inner case x 12 bottles)

Approved by FDA under ANADA # 200-362

Reorder #014677

Questions?

(855) 724-3461

Distributed by:

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ITEM NUMBER



(01) 20840066501141

EXP. DATE



YYYY/MMM

LOT NUMBER



XXXX

CASE QUANTITY



XX

Made in U.S.A.

AH-014677-S-02

REV: 0723

240 mL

FRONT



**Indications:** For the treatment of fungal infections in dogs and cats caused by *Microsporum canis*, *Microsporum gypseum*, and *Trichophyton mentagrophytes*.

**Dosage:** Apply a light covering to affected areas, once daily for 2 to 4 weeks. See accompanying literature for full directions.

Avoid contact with eyes, since irritation may result.

Wash hands thoroughly after administration to avoid spread of fungal infection.

NDC: 11695-2221-8

# Miconazole nitrate 1% Spray

Topical antifungal agent for dogs and cats

**Active ingredient:**

Miconazole nitrate ..... 1.15%  
(equivalent to 1% miconazole base by weight)

**Storage:** Store at controlled room temperature between 15° to 30°C (59°-86°F). Keep container tightly closed when not in use.



**CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.**

**Not for Use in Humans  
Keep Out of Reach of Children**

Approved by FDA  
under ANADA # 200-362

8 fl oz (240 mL)

**Reorder #014678  
Questions? (855) 724-3461**

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AH-014678-L-03  
REV: 0323

Lot No. / Exp. Date

NO VARNISH





## Miconazole nitrate 1%

### Spray

Topical antifungal agent for dogs and cats.

**Description:** Miconazole nitrate 1% Spray is a synthetic antifungal agent for use in dogs and cats. It contains: 1.15% miconazole nitrate (equivalent to 1% miconazole base by weight), polyethylene glycol 400, and ethyl alcohol 55%.

**Indications:** Miconazole nitrate 1% Spray is indicated for the treatment of fungal infections in dogs and cats caused by *Microsporum canis*, *Microsporum gypseum*, and *Trichophyton mentagrophytes*.

**Precautions:** In the event of sensitization or irritation due to Miconazole nitrate 1% Spray, treatment should be discontinued. Avoid contact with eyes, since irritation may result. Wash hands thoroughly after administration to avoid spread of fungal infection.

**Dosage and administration:** Accurate diagnosis of the infecting organism is essential. Identification should be made either by direct microscopic examination of a mounting of infected tissue in a solution of potassium hydroxide, or by culture on an appropriate medium.

**Spray:** Spray affected areas from a distance of 2 to 4 inches to apply a light covering, once daily for 2 to 4 weeks. Do not allow pet to contact finished wood surfaces until pet is thoroughly dried.

Medication must be continued until the infecting organism is completely eradicated as indicated by appropriate clinical or laboratory examination. If no improvement is noticed within 2 weeks, diagnosis should be re-evaluated. Difficult cases may require treatment for 6 weeks.

General measures in regard to hygiene should be observed to control sources of infection or reinfection. Clipping of hair around and over the sites of infection should be done at the start of treatment and again as necessary.

**How supplied:** Miconazole nitrate 1% Spray is available in 120 mL and 240 mL bottles with spray misters.

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**CONTACT INFORMATION:** To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact First Priority, Inc. at (800) 650-4899 or [www.prioritycare.com](http://www.prioritycare.com). For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>

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400 Metro Place North  
Dublin, OH 43017  
[covetrus.com](http://covetrus.com)

REV: 0323



Approved by FDA  
under ANADA # 200-362

Covetrus  
Item # TP323CV

**Miconazole nitrate 1% Spray 8 fl oz (240 mL)**

12 Bottles, 240 mL each

<b>LOT NUMBER</b>	<b>EXP. DATE</b>	<b>QUANTITY</b>
		
XXXX	YYYY/MMM	XX

Rev. 03-23 Approved by FDA under ANADA # 200-362

Covetrus  
Item # TP323CV

**Miconazole nitrate 1% Spray 8 fl oz (240 mL)**

12 Bottles (1 inner case x 12 bottles)

<b>LOT NUMBER</b>	<b>EXP. DATE</b>	<b>CASE QUANTITY</b>
		
XXXX	YYYY/MMM	XX

Rev. 03-23 Approved by FDA under ANADA # 200-362

**MICONAZOLE NITRATE 1%**

miconazole spray

**Product Information**

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:11695-2221
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>MICONAZOLE NITRATE</b> (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	11.5 mg in 1 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11695-2221-2	72 in 1 CASE		

<b>1</b>		60 mL in 1 BOTTLE, DROPPER		
<b>2</b>	NDC:11695-2221-4	12 in 1 CASE		
<b>2</b>		120 mL in 1 BOTTLE, SPRAY		
<b>3</b>	NDC:11695-2221-8	12 in 1 CASE		
<b>3</b>		240 mL in 1 BOTTLE, SPRAY		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200362	09/21/2023	

**Labeler** - Butler Animal health Supply, LLC dba Covetrus North America (603750329)

## Establishment

Name	Address	ID/FEI	Business Operations
FIRST PRIORITY INCORPORATED		179925722	manufacture, label

Revised: 3/2024

Butler Animal health Supply, LLC dba Covetrus North America