

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

**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

2 fl oz (60 mL)

4 fl oz (120 mL)

8 fl oz (240 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

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-04 REV: 0723

Questions? (855) 724-3461

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

Description:

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

Precautions:

In the event of sensitization or irritation due to Miconazole nitrate 1% Lotion & 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.

How supplied:

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 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. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>

Distributed by:
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400 Metro Place North
Dublin, OH 43017
covetrus.com



Approved by FDA under ANADA # 200-362

60 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: 11695-2221-2

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

Distributed by:
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AH-014676-L-04
REV: 0723

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:

Covetrus® North America

400 Metro Place North

Dublin, OH 43017

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



Reorder #014676

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

Questions?

(855) 724-3461

Distributed by:

Covetrus® North America

400 Metro Place North

Dublin, OH 43017

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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

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. 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

covetrus 



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

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



AH-014677-L-04
REV: 0723



Miconazole nitrate 1% Spray 8 fl oz (240 mL) Reorder #014678

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

Questions?
(855) 724-3461
Distributed by:
Covetrus® North America
400 Metro Place North
Dublin, OH 43017
covetrus.com

ITEM NUMBER



(01) 20840066501158

EXP. DATE



YYYY/MMM

LOT NUMBER



XXXX

CASE QUANTITY



XX

Made in U.S.A.
AH-014678-S-02
REV: 0723



Miconazole nitrate 1% Spray 4 fl oz (120 mL) Reorder #014677

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

Questions?
(855) 724-3461
Distributed by:
Covetrus® North America
400 Metro Place North
Dublin, OH 43017
covetrus.com

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

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

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

AH-014678-L-04
REV: 0723

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 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>

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400 Metro Place North
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covetrus.com

REV: 0723



Approved by FDA
under ANADA # 200-362



Miconazole nitrate 1% Spray 8 fl oz (240 mL) Reorder #014678

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

Questions?

(855) 724-3461

Distributed by:

Covetrus® North America

400 Metro Place North

Dublin, OH 43017

covetrus.com

ITEM NUMBER



(01) 20840066501158

EXP. DATE



YYYY/MMM

LOT NUMBER



XXXX

CASE QUANTITY



XX

Made in U.S.A.

AH-014678-S-02

REV: 0723



Miconazole nitrate 1% Spray 8 fl oz (240 mL) Reorder #014678

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

Questions?

(855) 724-3461

Distributed by:

Covetrus® North America

400 Metro Place North

Dublin, OH 43017

covetrus.com

ITEM NUMBER



(01) 20840066501158

EXP. DATE



YYYY/MMM

LOT NUMBER



XXXX

CASE QUANTITY



XX

Made in U.S.A.

AH-014678-S-02

REV: 0723

MICONAZOLE NITRATE 1%

miconazole spray

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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MICONAZOLE NITRATE (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		
1		60 mL in 1 BOTTLE, DROPPER		
2	NDC:11695-2221-4	12 in 1 CASE		
2		120 mL in 1 BOTTLE, SPRAY		
3	NDC:11695-2221-8	12 in 1 CASE		
3		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: 8/2024

Butler Animal health Supply, LLC dba Covetrus North America