

PHYTO KET- ketoconazole, phytosphingosine hydrochloride solution

Butler Animal Health Supply, LLC dba Covetrus North America

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

Phyto KET Antiseptic Flush

Active ingredients: Ketoconazole 0.1%, phytosphingosine HCl 0.01%.

Inactive ingredients: Water, SDA 40B 190 proof, nonoxynol-9, disodium EDTA, tromethamine, methylisothiazolinone.

Properties: Phyto KET antiseptic flush is an antiseptic (antibacterial and antifungal) solution for gentle cleansing and flushing of ears and skin. Contains ketoconazole for the management of yeasts and fungi, and preservatives for antibacterial activity. It also contains phytosphingosine, a pro-ceramide to help support a healthy skin barrier. Phytosphingosine HCl also has antiseptic properties.

Indications: For the antiseptic cleansing of skin and ears.

Directions for use: Shake well before use.

Skin cleaning: Apply liberally to the affected area(s). Use cotton or absorbent material to clean excess solution and wipe away debris. Do not allow the animal to lick the treated area until dry to prevent ingestion.

Ear flushing: Instill liberally into the ear canal while keeping the ear flap up. Gently massage the base of the ear for a few seconds. Wipe the interior flap with cotton or gauze.

Apply twice daily or as directed by your veterinarian. Wash hands after use.

Cautions: For external use on dogs, cats, and horses only. Avoid contact with the eyes. If eye contact occurs, rinse thoroughly and consult your veterinarian. If skin irritation occurs or increases, discontinue use and consult with your veterinarian. Do not use in the case of a suspected ruptured eardrum.

Storage: Store at room temperature. Do not freeze.

Questions? (855) 724-3461

Distributed by:

Covetrus North America

400 Metro Place North

Dublin, OH 43017

covetrus.com

PRINCIPAL DISPLAY PANEL - 4 OUNCE (118 mL) Bottle

covetrus

11695-7222-4

Phyto KET

Ketoconazole 0.1%,

phytosphingosine HCl 0.01%


Antiseptic Flush

Antiseptic solution for cleansing and flushing of ears and skin for dogs, cats and horses

For animal use only

Keep out of reach of children

Net Contents: 4 fl oz (118 mL)




Active ingredients: Ketoconazole 0.1%,
phytosphingosine HCl 0.01%.

Inactive ingredients: Water, SDA 40B 190 proof,
nonoxynol-9, disodium EDTA, tromethamine,
methylisothiazolinone.

Properties: Phyto KET antiseptic flush is an
antiseptic (antibacterial and antifungal) solution for
gentle cleansing and flushing of ears and skin.
Contains ketoconazole for the management of
yeasts and fungi, and preservatives for antibacterial
activity. It also contains phytosphingosine, a
pro-ceramide to help support a healthy skin barrier.
Phytosphingosine HCl also has antiseptic properties.

Indications: For the antiseptic cleansing of skin
and ears.



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F40210D-US 18-V1-v2

NDC: 11695-7222-4

Phyto KET

Ketoconazole 0.1%,
phytosphingosine HCl 0.01%

Antiseptic Flush

Antiseptic solution for cleansing and
flushing of ears and skin for dogs, cats,
and horses

For animal use only
Keep out of reach of children

Net contents: 4 fl oz (118 mL)

Directions for use: Shake well before use.
Skin cleaning: Apply liberally to the affected area(s). Use
cotton or absorbent material to clean excess solution and
wipe away debris. Do not allow the animal to lick the
treated area until dry to prevent ingestion. **Ear flushing:**
Instill liberally into the ear canal while keeping the ear
flap up. Gently massage the base of the ear for a few
seconds. Wipe the interior flap with cotton or gauze.
Apply twice daily or as directed by your veterinarian.
Wash hands after use.

Cautions: For external use only on dogs, cats, and
horses. Avoid contact with eyes. If eye contact occurs,
rinse thoroughly and consult your veterinarian. If skin
irritation occurs or increases, discontinue use and
consult with your veterinarian. Do not use in the case of
a suspected ruptured eardrum.

Storage: Store at room temperature. Do not freeze.

Reorder #038184
Questions? (855) 724-3461
AH-038184-02
REV: 0819

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

PRINCIPAL DISPLAY PANEL - 16 OUNCE (473 mL) Bottle

covetrus

11695-7222-6

Phyto KET

Ketoconazole 0.1%,

phytosphingosine HCl 0.01%

Antiseptic Flush

Antiseptic solution for cleansing and flushing of ears and skin for dogs, cats and horses

For animal use only

Keep out of reach of children

Net Contents: 16 fl oz (473 mL)

NDC: 11695-7222-6

Phyto KET

Ketoconazole 0.1%,
phytosphingosine HCl 0.01%

Antiseptic Flush

Antiseptic solution for cleansing and
flushing of ears and skin for dogs, cats,
and horses

For animal use only
Keep out of reach of children

Net contents: 16 fl oz (473 mL)

Active ingredients: Ketoconazole 0.1%, phytosphingosine HCl 0.01%.**Inactive ingredients:** Water, SDA 40B 190 proof, nonoxynol-9, disodium EDTA, tromethamine, methylisothiazolinone.**Properties:** Phyto KET antiseptic flush is an antiseptic (antibacterial and antifungal) solution for gentle cleansing and flushing of ears and skin. Contains ketoconazole for the management of yeasts and fungi, and preservatives for antibacterial activity. It also contains phytosphingosine, a pro-ceramide to help support a healthy skin barrier. Phytosphingosine HCl also has antiseptic properties.**Indications:** For the antiseptic cleansing of skin and ears.**Directions for use:** Shake well before use.**Skin cleaning:** Apply liberally to the affected area(s). Use cotton or absorbent material to clean excess solution and wipe away debris. Do not allow the animal to lick the treated area until dry to prevent ingestion.**Ear flushing:** Instill liberally into the ear canal while keeping the ear flap up. Gently massage the base of the ear for a few seconds. Wipe the interior flap with cotton or gauze.

Apply twice daily or as directed by your veterinarian. Wash hands after use.

Cautions: For external use on dogs, cats, and horses only. Avoid contact with the eyes. If eye contact occurs, rinse thoroughly and consult your veterinarian. If skin irritation occurs or increases, discontinue use and consult with your veterinarian. Do not use in the case of a suspected ruptured eardrum.**Storage:** Store at room temperature. Do not freeze.**Reorder #038185****Questions?** (855) 724-3461AH-038185-02
REV: 0819Distributed by:
Covetrus North America
400 Metro Place North
Dublin, OH 43017
covetrus.com

F40230D-US 18-P1-v2

PHYTO KET

ketoconazole, phytosphingosine hydrochloride solution

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:11695-7222
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
KETOCONAZOLE (UNII: R9400W927I) (KETOCONAZOLE - UNII:R9400W927I)	KETOCONAZOLE	1 mg in 1 mL
PHYTOSPHINGOSINE HYDROCHLORIDE (UNII: TT871XV7TU) (PHYTOSPHINGOSINE - UNII:GIN46U9Q2Q)	PHYTOSPHINGOSINE HYDROCHLORIDE	0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R)					
ALCOHOL (UNII: 3K9958V90M)					
NONOXYNOL-9 (UNII: 48Q180SH9T)					
TROMETHAMINE (UNII: 023C2WHX2V)					
EDETATE DISODIUM (UNII: 7FLD91C86K)					
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)					
Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:11695-7222-4	118 mL in 1 BOTTLE, PLASTIC			
2	NDC:11695-7222-6	473 mL in 1 BOTTLE, PLASTIC			
Marketing Information					
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other			01/01/2020		

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

Registrant - Ceva Sante Animale (261126049)