CERASOOTHE CK MOUSSE- chlorhexidine gluconate, ketoconazole liquid 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.

CeraSoothe CHX+KET

Antiseptic Mousse

Fragrance: Cucumber melon

A leave-on mousse with chlorhexidine and ketoconazole, antibacterial and antifungal ingredients for antiseptic activity on skin. Ceramides and avenanthramides are skin nourishing nutrients that moisturize and calm the skin. They also support the skin's natural immune system, and provide building blocks for renewed skin barrier integrity.

Active ingredients: Chlorhexidine gluconate 2%, ketoconazole 1%.

Inactive ingredients: Water, glycerin, polysorbate 20, propylene glycol, lactic acid, avena sativa (oat) kernal extract, ceramide EOP, ceramide EOS, ceramide NP, fragrance, potassium sorbate, methylisothiazolinone.

Indications: For use on cats, dogs and horses with bacterial or fungal skin infections that are responsive to chlorhexidine or ketoconazole.

Directions for use: Brush the fur and then apply on dry hair. Apply every 3 days for 2 to 3 weeks or as directed by your veterinarian. Wash hands after use.

<u>For localized application:</u> Dispense 1 - 2 pumps onto your palm and then apply on the targeted area(s). Massage into the skin until fully penetrated. Do not rinse, let air dry. Once dry, brush the fur again.

<u>For whole body application:</u> Dispense 1 or 2 pumps onto your palm and then apply on the skin and hair. Massage into the skin until fully penetrated. Repeat as many times and necessary to cover the whole body, avoiding the eyes and mouth. Do not rinse, let air dry. Once dry, brush the fur again.

<u>Dosage:</u>

Under 11 lbs: 1 pump per 2 lbs

11-88 lbs: 1 pump per 4 lbs

Over 88 lbs: 1 pump per 6 lbs

Dosage may be doubled for long-haired breeds. For deeper cleansing, use Ceraven CHX+KET antiseptic shampoo.

Cautions: For external use on cats, dogs and horses only. Avoid contact with eyes. In case of contact with eyes, rinse thoroughly and consult your veterinarian. If skin irritation occurs or increases, discontinue use and consult with your veterinarian.

Storage: Store at controlled 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 - 6.8 OUNCE (200 mL) Bottle

Inspired by veterinarians

CeraSoothe CHX+KET

Antiseptic Mousse

Fragrance: Cucumber melon

Chlorhexidine gluconate 2%, Ketoconazole 1%

Formulated for cats, dogs, and horses

Keep out of reach of children

For animal use only

NDC: 11695-6974-1

Net contents: 6.8 fl oz (200 mL)

covetrus



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Fragrance: Cucumber melon

Chlorhexidine gluconate 2% Ketoconazole 1%



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NDC: 11695-6974-1 Net contents: 6.8 fl oz (200mL)



A leave-on mousse with chlorhexidine and ketoconazole, antibacterial and antifungal ingredients for antiseptic activity on the skin. Ceramides and avenanthramides are skin nourishing nutrients that moisturize and calm the skin. They also support the skin's natural immune system and provide building blocks for renewed skin barrier integrity.

Active ingredients: Chlorhexidine gluconate 2%, ketoconazole 1%.

Inactive ingredients: Water, glycerin, polysorbate 20, propylene glycol, lactic acid, avena sativa (oat) kernel extract, ceramide EOP, ceramide EOS, ceramide NP, fragrance, potassium sorbate, methylisothiazolinone.

Indications: For use on cats, dogs, and horses with bacterial or fungal skin infections that are responsive to chlorhexidine or ketoconazole.

Directions for use: Brush the fur then apply product on dry hair. Apply every 3 days for 2-3 weeks or as directed by your veterinarian. Wash hands

<u>For localized application:</u> Dispense 1-2 pumps onto your palm, then apply on the targeted area(s). Massage into the skin until fully penetrated. Do not rinse, let air dry. Once dry, brush the fur again.

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For deeper cleansing, use CeraSoothe CHX+KET antiseptic shampoo. Cautions: For external use on cats, dogs, or horses only. Avoid contact with eyes. In case of contact with eyes, rinse thoroughly and consult your veterinarian. If skin irritation occurs or increases, discontinue use and

consult with your veterinarian.

Storage: Store at room temperature. Do not freeze.

Reorder #073101

Questions? (855) 724-3461 AH-073101-02 REV: 0621

400 Metro Place North Dublin, OH 43017 covetrus.com

G40910B-US 18-L1-v4

Distributed by: Covetrus North America



CeraSootheCHX+KET_Mousse_6oz.indd 1



10/4/21 4:25 PM

CERASOOTHE CK MOUSSE

chlorhexidine gluconate, ketoconazole liquid

Product Information

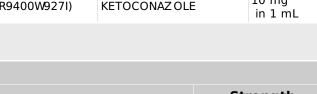
Route of Administration TOPICAL

Active Ingredient/Active Moiety

- 10.11.5 mg. 0.11.61.7 10.10.5 y					
Ingredient Name	Basis of Strength	Strength			
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	20 mg in 1 mL			
KETOCONAZOLE (UNII: R9400W927I) (KETOCONAZOLE - UNII:R9400W927I)	KETOCONAZ OLE	10 mg in 1 ml			

	Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)		

GLYCERIN (UNII: PDC6A3C0OX)





POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
LACTIC ACID (UNII: 33X04XA5AT)	
AVENANTHRAMIDES (UNII: 5PA41O4AIT)	
CERAMIDE 1 (UNII: 5THT33P7X7)	
CERAMIDE EOS (UNII: CROJ8RN66K)	
CERAMIDE NP (UNII: 4370DF050B)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11695-6974-1	200 mL in 1 BOTTLE, PLASTIC		

	Marketing Information				
Category	eting End Date				
unapproved drug other 04/16/2021					

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

Registrant - Ceva Sante Animale (261126049)

Revised: 5/2022 Butler Animal Health Supply, LLC dba Covetrus North America