DOUXO CALM- douxo calm serum gel Ceva Sante Animale

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.

DOUXO CALM SERUM

DOUXO®

Calm Serum

Phytosphingosine salicyloyl 0.2%

ACTIVE INGREDIENT: Phytosphingosine salicyloyl 0.2%

INACTIVE INGREDIENTS: Water, biosaccharide gum-4, butylene glycol, PEG-8, glycerin, paraffinum liquidum, rubus idaeus (raspberry) seed oil, cyclopentasiloxane, isostearyl alcohol, butylene glycol cocoate, phenoxyethanol, tocopheryl acetate, dimethicone, sodium dehydroacetate, acrylates/C10-30 alkyl acrylate crosspolymer, polysorbate-80, ethylcellulose, hinokitiol, sodium hydroxide, nordihydroguaiaretic acid.

INDICATIONS: For itching and inflammation associated with allergic conditions in dogs and cats.

DIRECTIONS FOR USE: Shake well before use. Apply once a day or as directed by your veterinarian. Hold the bottle approximately 8 inches from the skin. Depress spray nozzle to apply 2-3 sprays, which treats an area about 4 inches in diameter.

CAUTIONS: For external use on dogs or cats only. 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.

WARNING: Keep out of reach of children

STORAGE CONDITIONS: Store at room temperature. Do not freeze.

Manufactured for: Ceva Animal Health, LLC, Lenexa, KS 66215

1-800-999-0297, www.douxo.com

DOUXO® is a registered trademark of Ceva Santé Animale S.A.

PRINCIPAL DISPLAY PANEL - 60 mL (2 OUNCE) Bottle DOUXO®

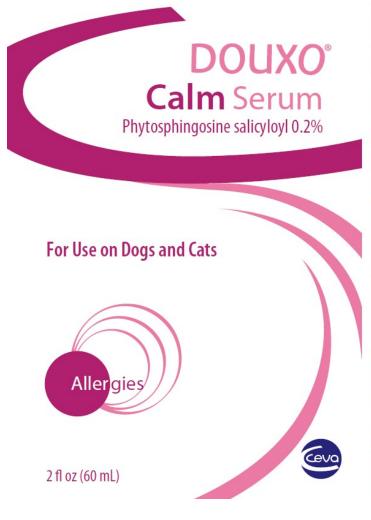
Calm Serum

Phytosphingosine salicyloyl 0.2%

For Use on Dogs and Cats

Allergies

2 fl. oz. (60 mL)



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DOUXO CALM

douxo calm serum gel

Product Information

Product Type OTC ANIMAL DRUG Item Code (Source) NDC:13744-160

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

SALICYLOYL PHYTOSPHINGOSINE (UNII: U891J4JCNH) (SALICYLOYL PHYTOSPHINGOSINE - UNII: U891J4JCNH)

Basis of Strength

SALICYLOYL
PHYTOSPHINGOSINE - UNII: U891J4JCNH)

SALICYLOYL
PHYTOSPHINGOSINE in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
BIOSACCHARIDE GUM-4 (UNII: 9XRL057X90)				
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)				

1,2-BUTYLENE GLYCOL MONOCOCOATE (UNII: XK3264896J)	
PEG-8 DIMETHICONE (UNII: GIA7T7640D)	
MINERAL OIL (UNII: T5L8T28FGP)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOSTEARYL ALCOHOL (UNII: Q6130CQ44Y)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER (60000 MPA.S) (UNII: 8Z5ZAL5H3V)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)	
SODIUM HINOKITIOL (UNII: 5MPS47D679)	
MASOPROCOL (UNII: 7BO8G1BYQU)	
ETHYLCELLULOSE (UNII: 7Z8S9VYZ4B)	

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:13744-160-01	60 mL in 1 BOTTLE, SPRAY					

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved drug other		04/30/2019			

Labeler - Ceva Sante Animale (261126049)

Registrant - Ceva Sante Animale (261126049)

Revised: 4/2019 Ceva Sante Animale