DOUXO CALM- douxo calm micro-emulsion spray spray 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

Micro-emulsion Spray

ACTIVE INGREDIENTS: Phytosphingosine salicloyl 0.05%.

INACTIVE INGREDIENTS: Water, Hexyl Laurate, Glyceryl Stearate, Ceteareth-12, Cetearyl Alcohol, Glycerin, Rubus Idaeus (Rasberry) Seed Oil, Ceteareth-20, Quaternium-82, Dipropylene Glycol, Potassium Sorbate, Methylisothiazolinone, Hinokitiol, Sodium Hydroxide.

INDICATIONS: For use on dogs and cats only. For the management of pruritus and inflammation associated with allergic conditions.

DIRECTIONS FOR USE: Brush the hair coat against the natural fur line, then spray the product by holding the pump approx. 12 inches from the pet's body, thus dispending the product over the targeted area. The product will disperse naturally. Do not over apply.

Dosage: 1 spray per 10 lbs. of bodyweight.

Dosage may be doubled for long-haired breeds.

May be used as part of a management plan as recommended by your veterinarian.

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

WARNING: Keep out of the reach of children.

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

Authorized for sale through licensed veterinarians only.

Manufactured for Ceva Animal Health, LLC

Lenexa, KS 66215 | 1-800-999-0297

Douxo® is a registered trademark of Sogeval S.A.

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PRINCIPAL DISPLAY PANEL - 200 mL (6.8 OUNCE) Bottle

DOUXO®

Calm

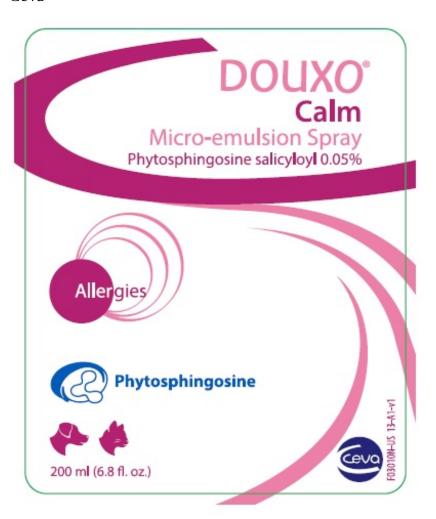
Micro-emulsion Spray

Phytosphingosine salicloyl 0.05%

Allergies

Phytospingosine

200 mL (6.8 fl. oz.)



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F03010N-US 14-A1-v1

DOUXO CALM

douxo calm micro-emulsion spray spray

Product Information					
Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:13744-124		
Route of Administration	TOPICAL				

Active Ingredient/Active Moiety						
Ingredient Name	Basis of Strength	Strength				
SALICYLOYL PHYTOSPHINGOSINE (UNII: U891J4JCNH) (SALICYLOYL PHYTOSPHINGOSINE - UNII: U891J4JCNH)	SALICYLOYL PHYTOSPHINGOSINE	0.5 mg in 1 mL				

Inactive Ingredients				
Ingredient Name	Strength			
RASPBERRY SEED OIL (UNII: 9S8867952A)				
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)				
QUATERNIUM-82 (UNII: AFS70NB1WJ)				
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 N	DC:13744-124-01	200 mL in 1 BOTTLE, SPRAY			
Marketing Information					

Marketing Start Date

0 1/0 1/20 16

Marketing End Date

Application Number or Monograph Citation

Labeler - Ceva Sante Animale (261126049)

Marketing Category

unapproved drug other

Registrant - Ceva Sante Animale (261126049)

Revised: 3/2016 Ceva Sante Animale