

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 salicyloyl 0.05%.

INACTIVE INGREDIENTS: Water, Hexyl Laurate, Glyceryl Stearate, Cetareth-12, Cetaryl Alcohol, Glycerin, Rubus Idaeus (Raspberry) Seed Oil, Cetareth-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 dispensing 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.

©2015 Ceva Animal Health, LLC

PRINCIPAL DISPLAY PANEL - 200 mL (6.8 OUNCE) Bottle

DOUXO®

Calm

Micro-emulsion Spray

Phytosphingosine salicyloyl 0.05%

Allergies

Phytosphingosine


200 mL (6.8 fl. oz.)

Ceva


DOUXO[®]
Calm
Micro-emulsion Spray
Phytosphingosine salicyloyl 0.05%

Allergies

Phytosphingosine



200 ml (6.8 fl. oz.)

 **Ceva**
F03010H-US 13-A1-V1

ACTIVE INGREDIENTS: Phytosphingosine salicyloyl 0.05%.

INACTIVE INGREDIENTS: Water, Hexyl Laurate, Glyceryl Stearate, Cetareth-12, Cetearyl Alcohol, Glycerin, Rubus Idaeus (Raspberry) Seed Oil, Cetareth-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 dispensing 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 in 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.
©2015 Ceva Animal Health, LLC

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)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2016	

Labeler - Ceva Sante Animale (261126049)**Registrant** - Ceva Sante Animale (261126049)

Revised: 3/2016

Ceva Sante Animale