

DOUXO CALM MOUSSE- phytosphingosine liquid
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 Mousse

ACTIVE INGREDIENTS: Phytosphingosine HCL 0.05%.

INACTIVE INGREDIENTS: Water, Capryl/Capramidopropyl Betaine, Diethylhexyl Carbonate, Polyglyceryl-4 Laurate, Phenoxyethanol, Dilauryl Citrate, Glycerin, Spent Grain Wax, Butyrospermum Parkii (Shea Butter) Extract, Argania Spinosa Kernel Oil, Avena Sativa (Oat) Kernel Extract, Potassium Sorbate, Ceramide 3, Ceramide 6-II, Ceramide 1, Cholesterol, Sodium Lauroyl Lactylate, Carbomer, Xanthan Gum, Butylene Glycol, Saccharomyces Cerevisiae Extract, Hydrogenated Polyisobutene, Cetareth-20, Phenoxyethanol, Polyquaternium 51, Fragrance, Sodium Hydroxide.

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

DIRECTIONS FOR USE: Shake well before use.

For localized application: Apply on dry hair. Brush the hair coat. Dispense 1 or 2 pumps in the hand and then apply on the targeted area, massage into the skin until fully penetrated. Do not rinse. Let air dry. Once dry, brush the hair coat again.

For whole body application: Apply on dry hair. Brush the hair coat. Dispense 1 or 2 pumps in the hand and then apply on the skin and hair. Massage into the skin until fully penetrated. Repeat as many times as necessary to cover the whole body, avoiding areas around the eyes and mouth. Do not rinse. Let air dry. Once dry, brush the hair coat again.

Dosage:

Under 11 lbs: 1 pump per 2 lbs

12-88 lbs: 1 pump per 4 lbs

Over 89 lbs: 1 pump per 6 lbs

Dosage can be doubled for long-haired breeds.

Apply every 3 days for 2 to 3 weeks or as recommended by your veterinarian. 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. If contact with the eyes occurs, rinse thoroughly and consult your veterinarian. If irritation occurs or increases, discontinue use and consult 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 Mousse

Phytosphingosine HCL 0.05%

Allergies

Phytosphingosine

200 mL (6.8 fl. oz.)

Ceva

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F030100-US 01-A1-v1

DOUXO CALM MOUSSE

phytosphingosine liquid

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:13744-125
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
PHYTOSPHINGOSINE HYDROCHLORIDE (UNII: TT871XV7TU) (PHYTOSPHINGOSINE - UNII:GIN46U9Q2Q)	PHYTOSPHINGOSINE HYDROCHLORIDE	.5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CAPRYL/CAPRAMIDOPROPYL BETAINE (UNII: 231HBZT9NE)	
DIETHYLHEXYL CARBONATE (UNII: YCD50O0Z6L)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DILAURYL CITRATE (UNII: 5OYS3G306B)	
GLYCERIN (UNII: PDC6A3C0OX)	
OAT (UNII: Z6J799EAJK)	
SHEA BUTTER (UNII: K49155WL9Y)	
ARGANIA SPINOSA SEED (UNII: 8H7X7XB54H)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CERAMIDE 3 (UNII: 4370DF050B)	
CERAMIDE 6 II (UNII: F1X8L2B00J)	
CERAMIDE 1 (UNII: 5THT33P7X7)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
XANTHAN GUM (UNII: TTV12P4NEE)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SACCHAROMYCES CEREVISIAE (UNII: 978D8U419H)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13744-125-01	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)

