

DOUXO- doux calm solution
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 Shampoo

ACTIVE INGREDIENT: Phytosphingosine HCL 0.05%.

INACTIVE INGREDIENTS: Water, Cocamidopropyl Betaine, Sodium Laureth Sulfate, Decyl Glucoside, Polyoxyethylene (PEG-7) Glyceryl Monococoate, Acrylates/Steareth-20 Methacrylate Copolymer, Cocoglucoside, Coconut Alcohol, Spent Grain Wax, Butyrospermum Parkii (Shea Butter) Extract, Argania Spinosa Kernel Oil, Cyclopentasiloxane, Avena Sativa (Oat) Kernel Extract, Glycerin, Potassium Sorbate, Ceramide 3, Ceramide 6 II, Ceramide 1, Cholesterol, Sodium Lauroyl Lactylate, Carbomer, Xanthan Gum, Phenoxyethanol, Polyquaternium-10, Butylene Glycol, Saccharomyces Cerevisiae Extract, Polyquaternium-51, Methylisothiazolinone, Sodium Hydroxide.

PROPERTIES: DOUXO® Calm Shampoo is a formulation designed to support sensitive and allergic skin in dogs and cats. It is soap-free, and contains highly purified fraction of oatmeal, plant extracts and lipids to help soothe irritations, moisturize and help restore the skin lipid content. DOUXO®Calm Shampoo also contains Phytosphingosine, a Ceva exclusive pro-ceramide to help support a healthy skin barrier.

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

DIRECTIONS FOR USE: Wet the animal with warm water and apply DOUXO® Calm Shampoo. Massage into the wet hair coat. Allow to remain on the hair coat for 5 to 10 minutes before rinsing thoroughly with clean water. Repeat if needed.

Shampoo 2 to 3 times per week, for 1 to 2 weeks, or as directed 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. 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 Shampoo

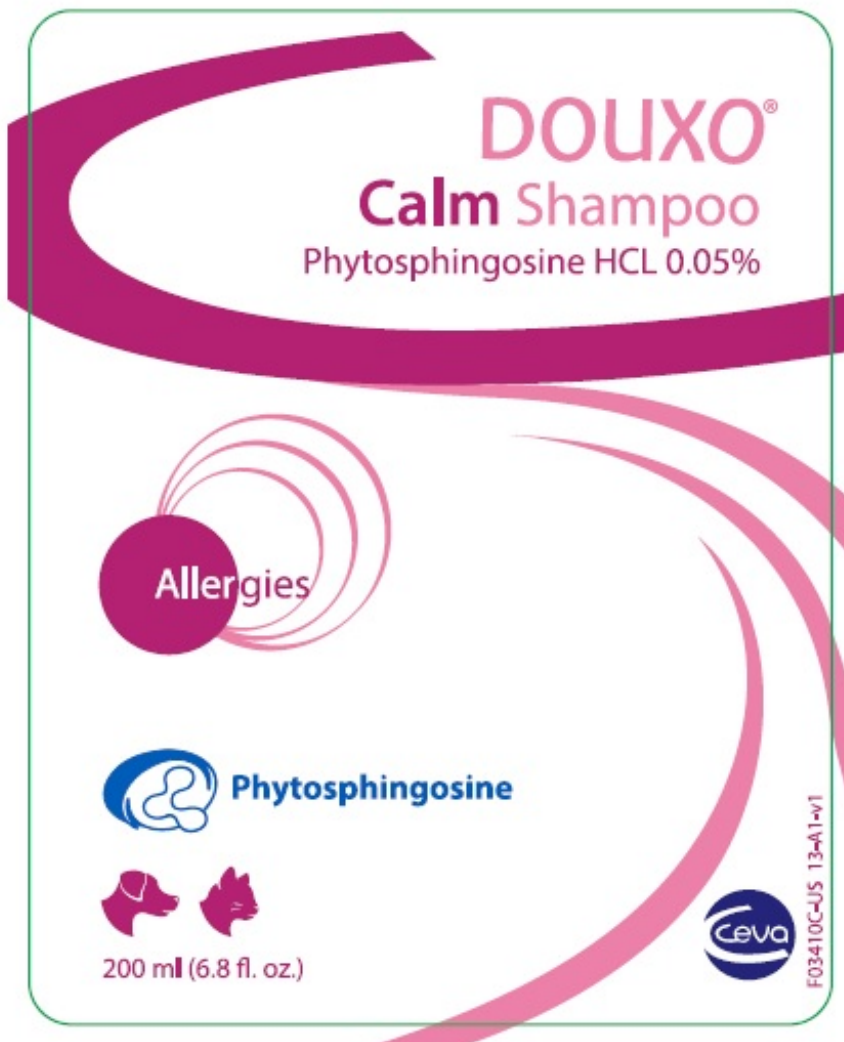
Phytosphingosine HCl 0.05%

Allergies

Phytosphingosine

200 ml (6.8 fl. oz.)

Ceva



ACTIVE INGREDIENT: Phytosphingosine HCL 0.05%.

INACTIVE INGREDIENTS: Water, Cocamidopropyl Betaine, Sodium Laureth Sulfate, Decyl Glucoside, Polyoxyethylene (PEG-7) Glyceryl Monococoate, Acrylates/Steareth-20 Methacrylate Copolymer, Cocoglucoside, Coconut Alcohol, Spent Grain Wax, Butyrospermum Parkii (Shea Butter) Extract, Argania Spinosa Kernel Oil, Cyclopentasiloxane, Avena Sativa (Oat) Kernel Extract, Glycerin, Potassium Sorbate, Ceramide 3, Ceramide 6 II, Ceramide 1, Cholesterol, Sodium Lauroyl Lactylate, Carbomer, Xanthan Gum, Phenoxyethanol, Polyquaternium-10, Butylene Glycol, Saccharomyces Cerevisiae Extract, Polyquaternium 51, Methylisothiazolinone, Sodium Hydroxide.

PROPERTIES: DOUXO® Calm Shampoo is a formulation designed to support sensitive and allergic skin in dogs and cats. It is soap-free, and contains highly purified fraction of oatmeal, plant extracts and lipids to help soothe irritations, moisturize and help restore the skin lipid content. DOUXO® Calm Shampoo also contains Phytosphingosine, a Ceva exclusive pro-ceramide to help support a healthy skin barrier.

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

DIRECTIONS FOR USE: Wet the animal with warm water and apply DOUXO® Calm Shampoo. Massage into the wet hair coat. Allow to remain on the hair coat for 5 to 10 minutes before rinsing thoroughly with clean water. Repeat if needed. Shampoo 2 to 3 times per week, for 1 to 2 weeks, or as directed 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. 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

F03410C-US 14-A1-v1

PRINCIPAL DISPLAY PANEL - 500 mL (16.9 OUNCE) Bottle

DOUXO®

Calm Shampoo

Phytosphingosine HCL 0.05%

Allergies

Phytosphingosine

500 ml (16.9 fl. oz.)

Ceva

DOUXO[®]

Calm Shampoo

Phytosphingosine HCL 0.05%

Allergies



Phytosphingosine



500 ml (16.9 fl. oz.)



F034208-US 13-A1-v1

ACTIVE INGREDIENT: Phytosphingosine HCL 0.05%.

INACTIVE INGREDIENTS: Water, Cocamidopropyl Betaine, Sodium Laureth Sulfate, Decyl Glucoside, Polyoxyethylene (PEG-7) Glyceryl Monococoate, Acrylates/Steareth-20 Methacrylate Copolymer, Cocoglucoside, Coconut Alcohol, Spent Grain Wax, Butyrospermum Parkii (Shea Butter) Extract, Argania Spinosa Kernel Oil, Cyclopentasiloxane, Avena Sativa (Oat) Kernel Extract, Glycerin, Potassium Sorbate, Ceramide 3, Ceramide 6 II, Ceramide 1, Cholesterol, Sodium Lauroyl Lactylate, Carbomer, Xanthan Gum, Phenoxyethanol, Polyquaternium-10, Butylene Glycol, Saccharomyces Cerevisiae Extract, Polyquaternium 51, Methylisothiazolinone, Sodium Hydroxide.

PROPERTIES: DOUXO® Calm Shampoo is a formulation designed to support sensitive and allergic skin in dogs and cats. It is soap-free, and contains highly purified fraction of oatmeal, plant extracts and lipids to help soothe irritations, moisturize and help restore the skin lipid content. DOUXO® Calm Shampoo also contains Phytosphingosine, a Ceva exclusive pro-ceramide to help support a healthy skin barrier.

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

DIRECTIONS FOR USE: Wet the animal with warm water and apply DOUXO® Calm Shampoo. Massage into the wet hair coat. Allow to remain on the hair coat for 5 to 10 minutes before rinsing thoroughly with clean water. Repeat if needed.

Shampoo 2 to 3 times per week, for 1 to 2 weeks, or as directed 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. 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

F034208-US 14-A1-v1

DOUXO

douxo calm solution

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:13744-123
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)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)	
ETHYL ACRYLATE/METHACRYLIC ACID/STEARETH-20 METHACRYLATE COPOLYMER (UNII: EPA1872R1N)	
COCO GLUCOSIDE (UNII: ICS790225B)	
COCONUT ALCOHOL (UNII: 13F4MW8Y9K)	
BARLEY (UNII: 5PWM7YLI7R)	
SHEA BUTTER (UNII: K49155WL9Y)	
ARGAN OIL (UNII: 4V59G5UW9X)	
CYCLOMETHICONE 4 (UNII: CZ227117JE)	
OAT (UNII: Z6J799EAJK)	
GLYCERIN (UNII: PDC6A3C0OX)	
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)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYQUATERNIUM-10 (400 CPS AT 2%) (UNII: HB1401PQFS)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SACCHAROMYCES CEREVISIAE (UNII: 978D8U419H)	
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13744-123-01	200 mL in 1 BOTTLE, PLASTIC		
2	NDC:13744-123-02	500 mL in 1 BOTTLE, PLASTIC		

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: 7/2019

Ceva Sante Animale