

DOUXO CALM- douxox 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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Phytosphingosine

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DOU06255

F03110J-US 01-A1-v2



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	Basis of Strength	Strength
SALICYLOYL PHYTOSPHINGOSINE (UNII: U891J4JCNH) (SALICYLOYL PHYTOSPHINGOSINE - UNII:U891J4JCNH)	SALICYLOYL PHYTOSPHINGOSINE	0.2 mg 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: GIA7T764OD)	
MINERAL OIL (UNII: T5L8T28FGP)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
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: 6OZP39ZG8H)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)	
SODIUM HINOKITOL (UNII: 5MPS47D679)	
MASOPROCOL (UNII: 7BO8G1BYQU)	
ETHYLCELLULOSE (UNII: 7Z8S9VYZ4B)	

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)