

DOUXO CALM- douxo calm 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 GEL

DOUXO®

Calm Gel

Phytosphingosine salicyloyl 0.20%

ACTIVE INGREDIENTS: Phytosphingosine salicyloyl 0.20%

INGREDIENTS: Water, Biosaccharide Gum-4, Butylene Glycol, PEG-8, Glycerin, Paraffinum Liquidum, Rubus Idaeus (Raspberry) Seed Oil, Isostearyl Alcohol, Butylene Glycol Cocoate, Ethylcellulose, Cyclopentasiloxane, Dimethicone, Tocopherol, Sodium Dihydroacetate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polysorbate 80, Sodium Hydroxide, Phenoxyethanol, Hinokitiol, Nordihydroguaiaretic Acid.

INDICATIONS: For use on dogs and cats only. For the management of skin inflammation.

DIRECTIONS FOR USE: Shake well before use. Spray directly on the skin by holding the pump approximately 8 inches from the skin. Apply once a day or as directed 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 skin 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 - 60 mL (2 OUNCE) Bottle

DOUXO®

Calm Gel

Phytosphingosine salicyloyl 0.20%

Allergies

60 mL (2 fl. oz.)

CEVA

DOUXO[®]
Calm Gel
Phytosphingosine salicyloyl 0.20%

Allergies

Phytosphingosine

60 ml (2 fl. oz.)

ACTIVE INGREDIENTS: Phytosphingosine salicyloyl 0.20%.

INACTIVE INGREDIENTS: Water, Biosaccharide Gum-4, Butylene Glycol, PEG-8, Glycerin, Paraffinum Liquidum, Rubus Idaeus (Raspberry) Seed Oil, Isostearyl Alcohol, Butylene Glycol Cocoate, Ethylcellulose, Cyclopentasiloxane, Dimethicone, Tocopherol, Sodium Dehydroacetate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polysorbate 80, Sodium Hydroxide, Phenoxyethanol, Hinokitiol, Nordihydroguaiaretic Acid.

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DOUXO CALM

douxo calm gel

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:13744-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLOYL PHYTOSPHINGOSINE (UNII: U891J4JCNH) (SALICYLOYL PHYTOSPHINGOSINE - UNII:U891J4JCNH)	SALICYLOYL PHYTOSPHINGOSINE	2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BIO SACCHARIDE GUM-4 (UNII: 9XRL057X90)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PEG-8 DIMETHICONE (UNII: GIA7T764OD)	
GLYCERIN (UNII: PDC6A3C0OX)	
MINERAL OIL (UNII: T5L8T28FGP)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
ISOSTEARYL ALCOHOL (UNII: Q6130CQ44Y)	

COCONUT OIL GLYCERETH-8 ESTERS (UNII: 9V234MGT7F)
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)
CYCLOMETHICONE 5 (UNII: 0THF5PC10R)
DIMETHICONE (UNII: 92RU3N3Y1O)
TOCOPHEROL (UNII: R0ZB2556P8)
SODIUM DEHYDRO ACETATE (UNII: 8W46YN971G)
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
SODIUM HINOKITIOL (UNII: 5MPS47D679)
MASOPROCOL (UNII: 7BO8G1BYQU)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13744-101-01	60 mL in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/01/2015	

Labeler - Ceva Sante Animale (261126049)

Registrant - Ceva Sante Animale (261126049)