

DOUXO MICELLAR- phytosphingosine salicyloyl 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 MICELLAR SOLUTION

DOUXO®

Micellar Solution

Phytosphingosine Salicyloyl 0.05%

ACTIVE INGREDIENT: Phytosphingosine Salicyloyl 0.05%

INGREDIENTS: Water, Polysorbate 80, SD Alcohol 40-B, Propylene Glycol, Laureth-9, Poloxamer 184, Imidazolidinyl Urea, Phenoxyethanol, Potassium Sorbate, Biosaccharide Gum-2, Citric acid, Fragrance.

PROPERTIES: Douxo® Micellar Solution contains micellar technology and soothing agents help emulsify and wash out waxy debris without drying the skin. The solution is non-greasy and non-staining. Douxo® Micellar Solution also contains phytosphingosine, a pro-ceramide to help support a healthy skin barrier.

INDICATIONS: For use in dogs and cats for cleaning of the ear canal, eye contours and skin folds. May be used on clean soiled and matted hair, or greasy skin.

DIRECTIONS FOR USE: Shake well before use. For ear cleaning, ask your veterinarian which of the following protocols is best for your pet:

- 1) Moisten a cotton ball with solution and place in the entrance of the ear canal; OR
- 2) Hold the ear flap upwards and fill the ear canal with solution.

Then gently massage the base of the ear for 60 seconds. Remove the cotton ball (if used) and allow the pet to shake its head. Gently wipe away visible debris and excess solution with a clean, dry cotton ball.

To clean other areas of the skin, moisten absorbent material with solution and gently wipe the area to cleanse and remove debris. Repeat as necessary until clean.

CAUTIONS: For external use only; avoid contact with the eyes. If eye contact occurs, rinse thoroughly and consult with your veterinarian. If skin irritation occurs or increases, discontinue use and consult with your veterinarian. Do not use in the case of a suspected ruptured eardrum.

WARNING: Keep out of the 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 - 125 mL BOTTLE

DOUXO®

Micellar Solution

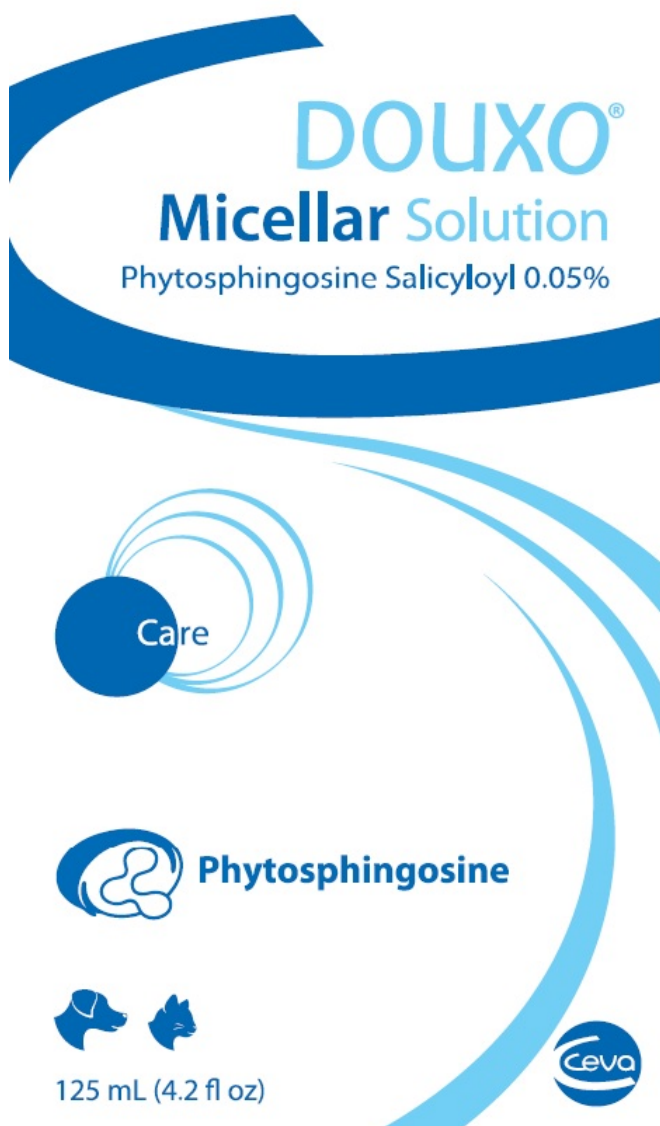
Phytosphingosine Salicyloyl 0.05%

Care

Phytosphingosine

125 ml (4.2 fl. oz.)

CEVA



ACTIVE INGREDIENT: Phytosphingosine Salicyloyl 0.05%

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G39310F 18-R1-v1

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PRINCIPAL DISPLAY PANEL - 250 mL BOTTLE

DOUXO®

Micellar Solution

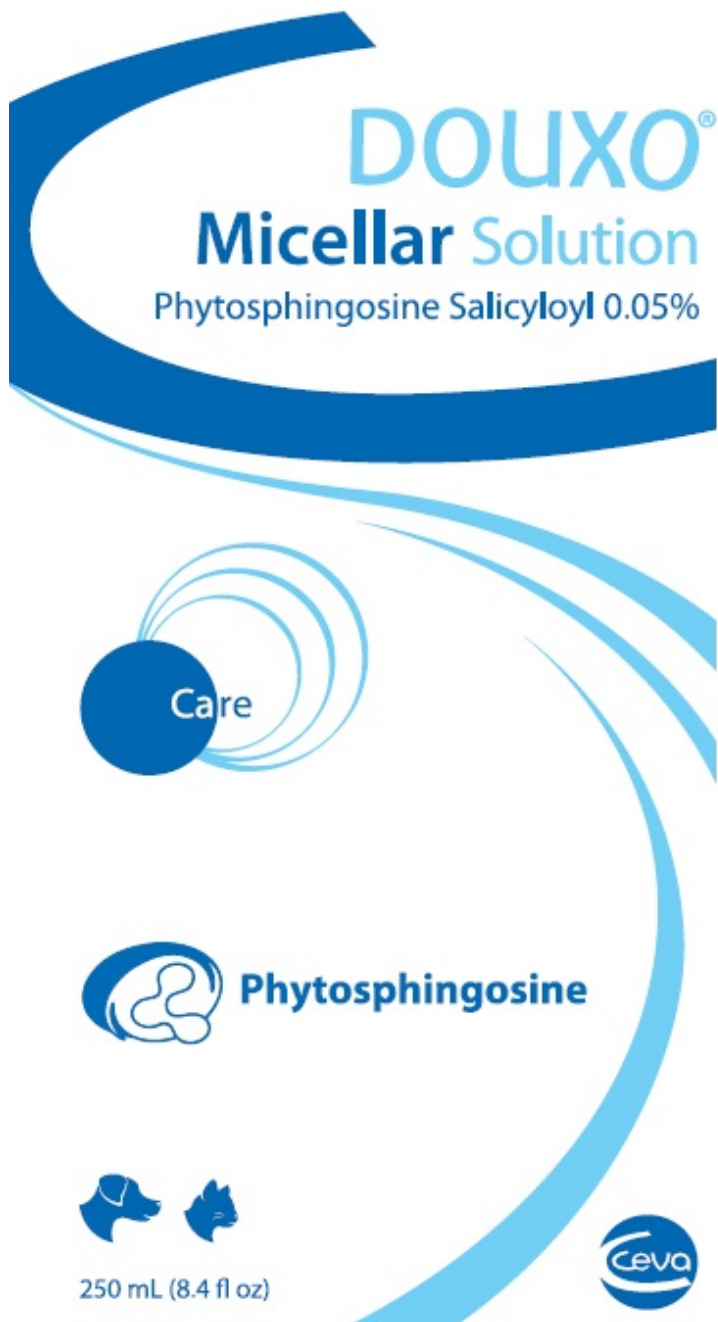
Phytosphingosine Salicyloyl 0.05%

Care

Phytosphingosine

250 ml (8.4 fl. oz.)

CEVA



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G39320F 18-T1-v1

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DOUXO MICELLAR

phytosphingosine salicyloyl solution

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:13744-158
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLOYL PHYTOSPHINGOSINE (UNII: U891J4JCNH) (PHYTOSPHINGOSINE - UNII:GIN46U9Q2Q)	SALICYLOYL PHYTOSPHINGOSINE	.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
LAURETH-9 PHOSPHATE (UNII: 0N8G76HI1O)	
POLOXAMER 184 (UNII: BIS92ZSF57)	
BIOSACCHARIDE GUM-2 (UNII: UVQ34I5XKQ)	
IMIDUREA (UNII: M629807ATL)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13744-158-01	125 mL in 1 BOTTLE, PLASTIC		
2	NDC:13744-158-02	250 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/05/2021	

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