DOUXO MICELLAR- phytosphingosine hydrochloride 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 HCL 0.02%

ACTIVE INGREDIENT: Phytosphingosine HCL 0.02%

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

PROPERTIES: Douxo® Micellar Solution is a formulation designed for the cleansing of ears in dogs and cats. The micellar technology and soothing agents help emulsify and wash out waxy debris without drying. The solution is non-greasy and non-staining. Douxo® Micellar Solution also contains Phytosphingosine, a Ceva exclusive pro-ceramide to help support a healthy skin barrier.

INDICATIONS: For use in dogs and cats only. For the cleaning of the ear canal. May be used for the cleansing of the eye contour or soiled and matted hairs. May be used for the cleansing of skin folds or the local cleaning of greasy skin associated with seborrheic conditions.

DIRECTIONS FOR USE:

Ear use: instill a few drops into the ear canal while keeping the ear flap up. Gently massage the base of the ear for a few seconds. Wipe the interior flap with cotton or gauze.

Skin cleaning: apply on the targeted area with cotton or gauze.

Apply every 3 days for 2 to 3 weeks or as recommended by your veterinarian. May be 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 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.

Availabl for sale through licensed veterinarians only.

Manufactured for Ceva Animal Health, LLC

Lenexa, KS 66215 I 1-800-999-0297

Douxo® is a registered trademark of Sogeval S.A.

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PRINCIPAL DISPLAY PANEL - 125 mL BOTTLE

DOUXO®

Micellar Solution

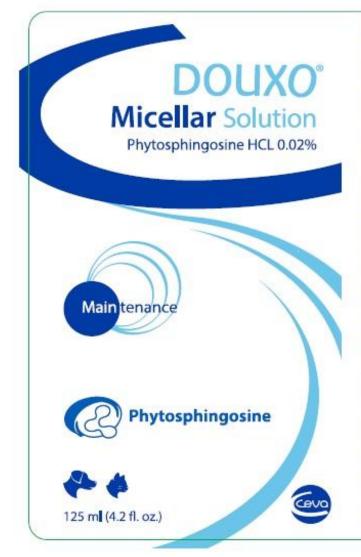
Phytosphingosine HCL 0.02%

Maintenance

Phytosphingosine

125 ml (4.2 fl. oz.)

CEVA



ACTIVE INGREDIENT: Phytosphingosine HCL 0.02%

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F048100-US 01-A1-v1

PRINCIPAL DISPLAY PANEL - 250 mL BOTTLE

DOUXO®

Micellar Solution

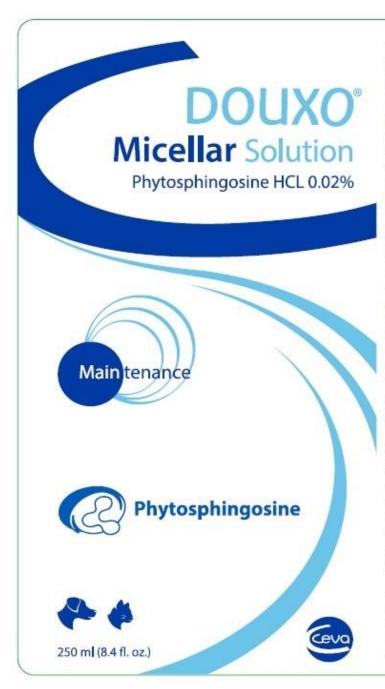
Phytosphingosine HCL 0.02%

Maintenance

Phytosphingosine

250 ml (8.4 fl. oz.)

CEVA



ACTIVE INGREDIENT: Phytosphingosine HCL 0.02%

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

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DOUXO MICELLAR

phytosphingosine hydrochloride solution

Product Information Product Type OTC ANIMAL DRUG Item Code (Source) NDC:13744-104 Route of Administration TOPICAL

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
PHYTOSPHINGOSINE HYDROCHLORIDE (UNII: TT871XV7TU) (PHYTOSPHINGOSINE - UNII:GIN46U9Q2Q)	PHYTOSPHINGOSINE HYDROCHLORIDE	.2 mg in 1 mL			

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
ALCOHOL (UNII: 3K9958V90M)				
POLYSORBATE 80 (UNII: 6 OZP39 ZG8 H)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
LAURETH-9 (UNII: 0 AWH8 BFG9 A)				
POLOXAMER 184 (UNII: BIS92ZSF57)				
BIO SACCHARIDE GUM-2 (UNII: UVQ34I5XKQ)				
IMIDUREA (UNII: M629807ATL)				
PHENO XYETHANO L (UNII: HIE492ZZ3T)				
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)				
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:13744-104-01	125 mL in 1 BOTTLE, PLASTIC				
2	NDC:13744-104-02	250 mL in 1 BOTTLE, PLASTIC				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		11/0 1/20 15		

Labeler - Ceva Sante Animale (261126049)

Registrant - Ceva Sante Animale (261126049)

Revised: 2/2016 Ceva Sante Animale