

**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.*

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**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.

Available 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 - 125 mL BOTTLE**

**DOUXO®**

**Micellar Solution**

**Phytosphingosine HCL 0.02%**

**Maintenance**

**Phytosphingosine**

125 ml (4.2 fl. oz.)

**CEVA**

**DOUXO<sup>®</sup>**  
**Micellar Solution**  
Phytosphingosine HCL 0.02%

**Maintenance**

**Phytosphingosine**

125 ml (4.2 fl. oz.)

**Ceva**

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F048100-US 01-A1-v1

**PRINCIPAL DISPLAY PANEL - 250 mL BOTTLE**

**DOUXO<sup>®</sup>**

**Micellar Solution**

**Phytosphingosine HCL 0.02%**

**Maintenance**

**Phytosphingosine**

250 ml (8.4 fl. oz.)

**CEVA**

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Phytosphingosine HCL 0.02%

Maintenance

Phytosphingosine



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F04820B-US 01-A1-v1

## DOUXO MICELLAR

phytosphingosine hydrochloride solution

### Product Information

<b>Product Type</b>	OTC ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:13744-104
<b>Route of Administration</b>	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: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
LAURETH-9 (UNII: 0AWH8BFG9A)	
POLOXAMER 184 (UNII: BIS92ZSF57)	
BIO SACCHARIDE 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:13744-104-01	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		11/01/2015	

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

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

Revised: 2/2016

Ceva Sante Animale