

DOUXO S3 CALM- ophytrium shampoo
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 S3™ CALM

OPHYTRIUM 0.75%

Soap, sulfate, paraben, phthalate, colorant and nanoparticle FREE

High tolerance formula. Hypoallergenic fragrance, adjusted pH. Formulated and tested by veterinary dermatology experts.

ACTIVE INGREDIENT: Ophytrium 0.75%

INACTIVE INGREDIENTS: Water, cocamidopropyl hydroxysultaine, sodium methyl lauroyl isethionate, sodium methyl cocoyl taurate, disodium laureth sulfosuccinate, sodium cocoamphoacetate, panthenol, jojoba esters, glycol distearate, pentavitin® (saccharide isomerate), niacinamide (Vit. PP), coco+vanilla hypoallergenic fragrance, phenoxyethanol, guar gum, acrylates/C10-30 alkyl acrylate, disodium EDTA, sodium benzoate, citric acid, sodium hydroxide.

PROPERTIES: Ophytrium is a purified, natural ingredient from the **S3 - Safe Skincare Selection**. Ophytrium has been carefully selected for its high tolerance and simultaneous threefold action on the skin's ecosystem:

- Helps support the skin's physical barrier for supple, hydrated skin
- Helps support the microbial flora for healthy skin
- Helps soothe irritated skin

INDICATIONS: For use on dogs or cats with itchy, irritated, or allergic skin. Helps soothe and hydrate the skin. Detangles the fur and leaves the coat soft and shiny.

DIRECTIONS FOR USE: Use one pump for every 4 lbs. Double the dosage for long and/or thick fur. Wet with cool water from the neck down. First, gently massage shampoo onto the problem area. Repeat on entire body and leave on for 5-10 minutes before rinsing. Repeat if necessary. Use DOUXO® S3 CALM Mousse for a leave-on solution.

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. Keep out of reach of children.

Store at room temperature.

"How to use" video www.douxo.com

Manufactured for Ceva Animal Health, LLC, Lenexa, KS 66215, 800-999-0297

Pentavitin® is a registered trademark of DSMP Assets B.V.

All other trademarks are owned by Ceva Santé Animale S.A. or its affiliates.

PRINCIPAL DISPLAY PANEL - 200 mL Bottle

DOUXO S3™

CALM

OPHYTRIUM 0.75%

soothing

ITCHY, IRRITATED SKIN

shampoo

For use on dogs or cats

6.7 fl oz (200 mL)

“How to use” video
www.douxo.com

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800-999-0297. Pentavitin® is a registered trademark of DSMIP.
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D98110P 18-L1-v1

PRINCIPAL DISPLAY PANEL - 500 mL Bottle

DOUXO S3™

CALM

OPHYTRIUM 0.75%

soothing

ITCHY, IRRITATED SKIN

shampoo

For use on dogs or cats

16.9 fl oz (500 mL)

DOUXO S3TM

CALM

OPHYTRIUM 0.75%



soothing
ITCHY,
IRRITATED SKIN
shampoo



For use on dogs or cats

16.9 fl oz (500 mL)



"How to use" video
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UPC

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FREE

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D98120F 18-M1-v1

DOUXO S3 CALM

ophytrium shampoo

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:13744-151
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OPHIOPOGON JAPONICUS ROOT (UNII: 90PS6JV9GZ) (OPHIOPOGON JAPONICUS ROOT - UNII:90PS6JV9GZ)	OPHIOPOGON JAPONICUS ROOT	7.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM HYDROLYZED JOJOBA ESTERS (UNII: CH428W5O62)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GUAR GUM (UNII: E891I637KE)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13744-151-01	200 mL in 1 BOTTLE, PLASTIC		
2	NDC:13744-151-02	500 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/25/2020	

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

Name	Address	ID/FEI	Business Operations
TriRx Huntsville Pharmaceutical Services, LLC		117090286	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
SOCIETE INDUSTRIELLE LIMOUSINE D'APPLICATION BIOLOGIQUE		492816616	api manufacture

Revised: 11/2020

Ceva Sante Animale