

DOUXO S3 CALM MOUSSE- ophytrium liquid
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

mousse

OPHYTRIUM 0.75%

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

Leave-on for longer lasting action. High tolerance formula. Hypoallergenic fragrance, adjusted pH. Formulated and tested by veterinary dermatology experts.

ACTIVE INGREDIENT: Ophytrium 0.75%

INACTIVE INGREDIENTS: Water, capryl/capramidopropyl betaine, phenoxyethanol, pentavitin® (saccharide isomerate), panthenol, niacinamide (vit. PP), coco+vanilla hypoallergenic fragrance, guar gum, PEG-40 hydrogenated castor oil, 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 while hydrating the skin. Detangles the fur and leaves the coat soft and shiny.

DIRECTIONS: Apply to a brushed, dry coat. First, gently massage onto the problem area until the mousse reaches the skin. Repeat this action all over the body, avoiding the eyes and mouth. Let air dry. Brush for a shiny coat. Wash hands after use. Use DOUXO® S3 CALM Shampoo to clean the skin if needed.



CAUTION: 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

mousse

leave-on

For use on dogs or cats

5 fl oz (150 mL)

DOUXO S3TM CALM
OPHYTRIUM 0.75%

WITH
OPHYTRIUM
FROM
S3
SAFE SKINCARE SELECTION

soothing
ITCHY,
IRRITATED SKIN
mousse
leave-on

For use on dogs or cats

5 fl oz (150 mL)

CEVA

FREE Leave-on for longer lasting action. High tolerance formula. Hypoallergenic fragrance, adjusted pH. Formulated and tested by veterinary dermatology experts.

ACTIVE INGREDIENT: Ophytrium 0.75%

INACTIVE INGREDIENTS: Water, capryl/capramidopropyl betaine, phenoxyethanol, pentavitin® (saccharide isomerate), panthenol, niacinamide (vit. PP), coco+vanilla hypoallergenic fragrance, guar gum, PEG-40 hydrogenated castor oil, 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 while hydrating the skin. Detangles the fur and leaves the coat soft and shiny.

DIRECTIONS: Apply to a brushed, dry coat. First, gently massage onto the problem area until the mousse reaches the skin. Repeat this action all over the body, avoiding the eyes and mouth. Let air dry. Brush for a shiny coat. Wash hands after use. Use DOUXO® S3 CALM Shampoo to clean the skin if needed.

Cat or dog ≤ 13 lbs	Dog > 13 lbs	1 pump per 2 lbs	1 pump per 4 lbs	Double the dosage for long and/or thick fur.
---------------------	--------------	------------------	------------------	--

Use 3 times a week for 3 weeks. Contains approx. 200 pumps.

CAUTION: 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.

UPC

Manufactured for Ceva Animal Health, LLC, Lenexa, KS 66215, 800.999.0207. "Ophytrium" is a registered trademark of DSM Nutris B.V. All other trademarks are owned by Ceva Santé Animales S.A. or its affiliates. www.douxo.com

DOUXO S3 CALM MOUSSE

ophytrium liquid

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:13744-150
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength

SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
PANTHENOL (UNII: WV9CM0O67Z)	
NIACINAMIDE (UNII: 25X51I8RD4)	
GUAR GUM (UNII: E89I1637KE)	
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13744-150-01	150 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)

Revised: 11/2020

Ceva Sante Animale