PHYTOVET MICELLAR OTIC CLEANSER- phytosphingosine hydrochloride solution Henry Schein Animal Health

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.

PHYTOVET MICELLAR OTIC CLEANSER

ACTIVE INGREDIENT: phytosphingosine HCI 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: Phyto Vet Micellar Otic Cleanser contains micellar technology and soothing agents to help emulsify and wash out waxy debris without drying. The solution is non-greasy and non-staining. Phyto Vet Micellar Otic Cleanser also contains phytosphingosine, a pro-ceramide to help support a healthy skin barrier.

INDICATIONS: For use in dogs and cats only. Ideal for cleaning the ear canal, eye contours and skin folds. May also be used to clean soiled and matted hair, or greasy skin associated with seborrheic conditions.

DIRECTIONS FOR USE: Shake well before use. For ear cleaning, ask your veterinarian which of the two 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 a cotton ball or gauze with the solution and gently wipe the area to cleanse and remove visible debris. Repeat as often as necessary until clean.

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.

STORAGE CONDITIONS: Store at room temperature. Do not freeze.

Questions? (855) 724-3461

Distributed by:

Henry Schein Animal Health

Dublin, OH 43017

www.henryscheinvet.com

PRINCIPAL DISPLAY PANEL - 125 mL BOTTLE

HENRY SCHEIN®

ANIMAL HEALTH

NDC #11695-7191-1

PHYTOVET MICELLAR

OTIC CLEANSER

Phytosphingosine HCl 0.02%

4.2 fl oz (125 mL)

FOR VETERINARY USE ONLY

KEEP OUT OF THE REACH OF CHILDREN



NDC #11695-7191-1

PHYTOVET MICELLAR OTIC CLEANSER

Phytosphingosine HCl 0.02%

4.2 fl oz (125 mL)

FOR VETERINARY USE ONLY
KEEP OUT OF THE REACH OF CHILDREN



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STORAGE CONDITIONS: Store at room temperature. Do not freeze.

Questions? (855) 724-3461

Reorder #057870

Distributed by: Henry Schein Animal Health Dublin, OH 43017 www.henryscheinvet.com

AH-057870-01 Rev: 12/15/2016



F04810V-US 01-R1-v1

PRINCIPAL DISPLAY PANEL - 250 mL BOTTLE

HENRY SCHEIN®

ANIMAL HEALTH

NDC #11695-7191-2

PHYTOVET MICELLAR OTIC CLEANSER

Phytosphingosine HCl 0.02%

8.4 fl oz (250 mL)

FOR VETERINARY USE ONLY

KEEP OUT OF THE REACH OF CHILDREN



NDC #11695-7191-2

PHYTOVET MICELLAR OTIC CLEANSER

Phytosphingosine HCl 0.02%

8.4 fl oz (250 mL)

FOR VETERINARY USE ONLY
KEEP OUT OF THE REACH OF CHILDREN

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STORAGE CONDITIONS: Store at room temperature. Do not freeze.

Questions? (855) 724-3461

Reorder #057871

Distributed by: Henry Schein Animal Health Dublin, OH 43017 www.henryscheinvet.com

AH-057871-01 Rev: 12/15/2016





F04820E-US 01-T1-v1

PHYTOVET MICELLAR OTIC CLEANSER

phytosphingosine hydrochloride solution

| Product Information | | | | | |
|-------------------------|-----------------|--------------------|----------------|--|--|
| Product Type | OTC ANIMAL DRUG | Item Code (Source) | NDC:11695-7191 | | |
| Route of Administration | TOPICAL | | | | |

| Active Ingredient/Active Moiety | | | | |
|--|-----------------------------------|-------------------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| PHYTOSPHINGOSINE HYDROCHLORIDE (UNII: TT871XV7TU) (PHYTOSPHINGOSINE - UNII:GIN46U9Q2Q) | PHYTOSPHINGOSINE HYDROCHLORIDE | 0.2 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) | | | |
| POLIDO CANO L (UNII: 0 AWH8 BFG9 A) | | | |
| POLOXAMER 184 (UNII: BIS92ZSF57) | | | |
| BIO SACCHARIDE GUM-2 (UNII: UVQ34I5XKQ) | | | |
| IMIDUREA (UNII: M629807ATL) | | | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | | | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | | | |
| CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP) | | | |

| Packaging | | | | | |
|--------------------|-----------------------------|----------------------|--------------------|--|--|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 NDC:11695-7191-1 | 125 mL in 1 BOTTLE, PLASTIC | | | | |
| 2 NDC:11695-7191-2 | 250 mL in 1 BOTTLE, PLASTIC | | | | |

| Marketing Information | | | | | |
|-----------------------|--|----------------------|--------------------|--|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | |
| unapproved drug other | | 02/07/2017 | | | |
| | | | | | |

Labeler - Henry Schein Animal Health (017880659)

Registrant - Ceva Sante Animale (261126049)

Revised: 2/2017 Henry Schein Animal Health