

ALLERMYL- piroctone olamine shampoo
Virbac AH, Inc.

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.

Allermyl® Medicated Shampoo

USES: ALLERMYL® Shampoo with S-I-S SKIN INNOVATIVE SCIENCE® Technology is a soothing shampoo for the management of allergic skin conditions. Specifically designed to meet the needs of dogs and cats with sensitive and itchy skin. ALLERMYL Shampoo is a unique micro-emulsified formulation which combines ingredients that help:

- Maintain skin barrier integrity
 - ◇ Moisturizing and soothing effects (**Skin Lipid Complex** combination)
- Support healthy skin with **S-I-S SKIN INNOVATIVE SCIENCE** Technology:
 - ◇ Provides micro-organism anti-adhesive effects (**Glycotechnology**)
 - ◇ Promotes natural skin microbial defenses (**Defensin technology**)
- Promote a healthy microbial balance in animals with allergic skin conditions (Piroctone Olamine)

ACTIVE INGREDIENTS: Piroctone Olamine 0.5% w/w

INACTIVE INGREDIENTS: Alkylpolyglucoside, Butylene Glycol, Citric Acid, Coco-Betaine, d-Galactose, d-Mannose, Disodium EDTA, l-Rhamnose, Laureth-2, Methylpropanediol, PEG-90 Glyceryl Isostearate, *Peumus boldus* Leaf Extract, Purified Water, Skin Lipid Complex (Ceramides, Fatty Acids), Sodium Laureth Sulfate, *Spiraea ulmaria* Extract, Vitamin F, Xanthan Gum

DIRECTIONS FOR USE: Shake well before use. Wet the hair coat with water and apply a thin line of shampoo from the base of the neck to the base of the tail. Massage shampoo over pet's body to ensure good contact with the skin. Allow to remain on hair coat for 5 to 10 minutes, then rinse thoroughly with clean water and repeat. May be used initially 2 to 3 times a week for 4 weeks, then reduce to once a week, or as directed by your veterinarian.

CAUTION: For animal use only. For external use only. Avoid contact with eyes or mucous membranes. Not for otic use. If undue skin irritation develops or increases, discontinue use and consult a veterinarian.

WARNING: EYE IRRITANT. Avoid contact with eyes. In case of contact, flush eyes with water and seek medical attention if irritation persists. Wash hands after using.

Keep out of reach of children.

STORAGE: Store at controlled room temperature 59° - 86°F (15° - 30°C).

QUESTIONS?

Virbac AH, Inc., P.O. Box 162059, Fort Worth, TX 76161

1-800-338-3659 us.virbac.com

302242-01

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Virbac, a pioneer in Veterinary Dermatology, offers a broad range of skin care products tailored to the individual needs of the pet, helping to improve quality of life.

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NDC 51311-071-16

Virbac

ALLERMYL®

(PIROCTONE OLAMINE)

**MEDICATED SHAMPOO
FOR DOGS AND CATS**

**FOR MANAGEMENT
OF ALLERGIC
SKIN CONDITIONS**

**HELPS MAINTAIN SKIN
BARRIER INTEGRITY &
MICROBIAL BALANCE**

S>I>S®

>SKIN

>INNOVATIVE

>SCIENCE

**SOOTHES &
MOISTURIZES**

16 FL. OZ. (473 mL)

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**SOOTHES &
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16 FL.OZ. (473 mL)

ALLERMYL

piroctone olamine shampoo

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:51311-071
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PIROCTONE OLAMINE (UNII: A4V5C6R9FB) (PIROCTONE - UNII:R49EFA73Q7)	PIROCTONE OLAMINE	0.5 mg in 1 mg

Inactive Ingredients

Ingredient Name	Strength
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
COCO-BETAINE (UNII: 03DH2IZ3FY)	
MANNOSE, D- (UNII: PHA4727WTP)	
PEUMUS BOLDUS LEAF (UNII: Q4EWM09M3O)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
LAURETH-2 (UNII: D4D38LT1L5)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51311-071-16	1 in 1 CARTON		
1		473 mg in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/01/2018	

Labeler - Virbac AH, Inc. (131568396)

Establishment

Name	Address	ID/FEI	Business Operations
Virbac Corporation		829166276	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Kumar Organic Products Limited		918155912	api manufacture