PSORIATAR (COAL TAR)- coal tar aerosol, foam Nivagen Pharmaceuticals, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Psoriatar™ (Coal Tar) Foam, 2% coal tar foam

Drug Facts

Active Ingredient

Coal Tar 2% (from Coal Tar Topical Solution USP, 10%)

Purpose

Psoriasis

Use

for the relief of symptons of psoriasis

Warnings

For external use only

Flammable

Avoid fire, flame, or smoking during and immediately following application.

Do not use

- for prolonged periods without consulting a doctor
- this product in or around the rectum or in the genital area or groin except on the advice of a doctor

Ask a doctor before use if you have a condition that covers large areas of the body.

Ask a doctor or pharmacist before use if you are using the product with other forms of psoriasis therapy such as ultraviolet radiation or prescription drugs.

When using this product

- avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water.
- use caution in exposing skin to sunlight after applying this product. It may increase your tendency to sunburn for up to 24 hours after application.
- Product can stain clothing, contact lenses and hair. To minimize staining, allow product to dry before contact.

Stop use and ask doctor if condition worsens or does not improve after regular use of this product as directed.

If pregnant or breast feeding, ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a poison control center right away.

Directions

- Shake the can before use.
- Invert the can to dispense. Upright dispensing will cause loss of propellant.
- Apply to affected areas one to four times daily or as directed by a doctor.

Other Information

- Contents under pressure. Do not puncture or incinerate.
- Store at 68°-77°F (20°-25°C).
- Do not expose to heat or at temperatures above 120°F (49°C).

Inactive Ingredients

Alcohol denatured, caprylic/capric triglyceride, ceteareth-20, cyclopentasiloxane, dimethicone, disodium edta, glycerin, hydroxypropyl methylcellulose, isobutane, isopropyl myristate, mentha piperita (peppermint) oil, phenoxyethanol, polysorbate 80, potassium sorbate, propane, sodium chloride, sodium citrate, stearic acid, water (aqua), xantham gum

Questions?

1-877-977-0687

PRINCIPAL DISPLAY PANEL - 100 g Can Label

75834-101-01 **PSORIASIS FOAM**

Psoriatar_{TM}

(Coal Tar) Foam 2%

NIVAGEN PHARMACEUTICALS

Net wt. 3.5 oz (100 g)

Nivagen Psoriatar™ (Coal Tar) Foam 2% is an emollient foam containing 10% coal tar topical solution (Liquor Carbonis Detergens) equivalent to 2% coal tar.

(from Coal Tar Topical Solution USP, 10%)

Use for the relief of symptons of psoriasis

Warnings

For external use only

Flammable

Avoid fire, flame, or smoking during and immediately following application.

Do not use

- · for prolonged periods without consulting a doctor
- this product in or around the rectum or in the genital area or groin except on the advice of a doctor

Ask a doctor before use if you have

a condition that covers large areas of the body

Ask a doctor or pharmacist before use if you are using the product with other forms of psoriasis therapy such as ultraviolet radiation or prescription drugs.

When using this product

- avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water.
- use caution in exposing skin to sunlight after applying this
 product. It may increase your tendency to sunburn for up
 to 24 hours after application.
- Product can stain clothing, contact lenses and hair. To minimize staining, allow product to dry before contact.

Stop use and ask doctor

if condition worsens or does not improve after regular use of this product as directed.

75834-101-01 PSORIASIS FOAM



Drug Facts (continued)

If pregnant or breast feeding, ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a poison control center right away.

Directions

- . Shake the can before use.
- Invert the can to dispense. Upright dispensing will cause loss of propellant.
- Apply to affected areas one to four times daily or as directed by a doctor.

Other Information

- · Contents under pressure. Do not puncture or incinerate.
- Store at 68°-77°F (20°-25°C).
- Do not expose to heat or at temperatures above 120°F (49°C).

Inactive Ingredients

Alcohol denatured, caprylic/capric triglyceride, ceteareth-20, cyclopentasiloxane, dimethicone, disodium edta, glycerin, hydroxypropyl methylocelludes, isobutane, isopropyl mysistate, mentha piperita (peppermint) oil, phenoxyethanol, polysorbate 80, potassium sorbate, propane, sodium chloride, sodium citrate, stearic acid, water (aqua), xantham gum

Questions? 1-877-977-0687

Made in USA Nivagen Pharmaceuticals, Inc. Sacramento. CA 95827



PSORIATAR (COAL TAR)

coal tar aerosol, foam

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:75834-101

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthCoal Tar (UNII: R533ESO2EC) (Coal Tar - UNII:R533ESO2EC)Coal Tar20 mg in 1 g

Inactive Ingredients

* II	01
Ingredient Name	Strength
Isopropyl Alcohol (UNII: ND2M416302)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Polyoxyl 20 Cetostearyl Ether (UNII: YRC528SWUY)	
Cyclomethicone 5 (UNII: 0THT5PCI0R)	
Dimethicone (UNII: 92RU3N3Y1O)	
Edetate Disodium (UNII: 7FLD91C86K)	
Glycerin (UNII: PDC6A3C0OX)	

Hypromelloses (UNII: 3NXW29V3WO)	
Isobutane (UNII: BXR49TP611)	
Isopropyl Myristate (UNII: 0 RE8 K4LNJS)	
Peppermint Oil (UNII: AV092KU4JH)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	
Potassium Sorbate (UNII: 1VPU26JZZ4)	
Propane (UNII: T75W9911L6)	
Sodium Chloride (UNII: 451W47IQ8X)	
Sodium Citrate, Unspecified Form (UNII: 1Q73Q2JULR)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Water (UNII: 059QF0KO0R)	
Xanthan Gum (UNII: TTV12P4NEE)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:75834-101-01	1 in 1 CARTON	05/15/2016	
1	100 g in 1 CAN; Type 0: Not a Combination Product		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH FINAL	part358H	05/15/2016			

Labeler - Nivagen Pharmaceuticals, Inc. (052032418)

Revised: 5/2016 Nivagen Pharmaceuticals, Inc.