

SCYTERA (COAL TAR) FOAM, 2% - coal tar foam, 2% aerosol, foam
DPT Laboratories, Ltd.

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.

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

Active Ingredient - Purpose

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

Purpose: Psoriasis

Use

For relief of the symptoms 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 a large area of your 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 breastfeeding

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 well 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°F to 77°F (20°C to 25°C)
- do not expose to heat or store at temperatures above 120°F (49°C)

Inactive Ingredients

Caprylic/capric triglyceride, cetareth 20, citric acid, cyclomethicone, dimethicone, EDTA disodium, glycerin, hydroxypropyl methyl cellulose, isopropyl myristate, peppermint oil, phenoxyethanol, potassium sorbate, purified water, sodium citrate, stearic acid, xanthan gum, hydrocarbon (propane/butane) propellant.

Questions?

1-888-966-8766

Warning

This product contains chemicals known to the state of California to cause cancer.

Patent Pending

Made in USA.

Marketed by:

Promius Pharma, LLC

Bridgewater, NJ 08807

Under license from

Foamix LTD, Israel

Scytera™ (Coal Tar)Foam 2%, 100 g

Carton and Can Label

NDC 67857-801-52

Psoriasis Foam

Scytera™

(Coal Tar) Foam 2%

Promius Pharma™

NET WT. 3.3 oz (100 g)

Scytera
(coal tar) Foam 2%

NDC 67857-801-52
Psoriasis Foam

Scytera
(coal tar) Foam 2%

PROMIUS
PHARMA
NET WT. 3.3 oz (100 g)

Scytera™ Foam is an emollient foam containing 10% coal tar topical solution (Liquid Carbona Detergens) equivalent to 2% coal tar.

Drug Facts

Active ingredient Purpose
Coal Tar 2%..... Psoriasis
(from Coal Tar Topical Solution USP, 10%)

Use for relief of the symptoms of psoriasis

Warnings

For external use only

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



NDC 67857-801-52
Psoriasis Foam

Scytera
(coal tar) Foam 2%

PROMIUS
PHARMA
NET WT. 3.3 oz (100 g)

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 store at temperatures above 120°F (49°C).

Inactive ingredients

Caprylic/capric triglyceride, ceteareth 20, citric acid, cyclomethicone, dimethicone, EDTA, sodium, glycerin, hydroxypropyl methyl cellulose, isopropyl myristate, piperazine oil, phenylethanol, potassium sorbate, purified water, sodium citrate, stearic acid, xanthan gum, hydrocarbon (propellant) propellant

Questions ?

1-888-968-8700

Patent Pending

Made in USA

Marketed by

Promius Pharma, LLC

Bridgewater, NJ 08807

Under license from

Foamix LTD, Israel



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001024
10706

Lot:

Exp:

<p>Scytera™ Foam is an emollient foam containing 10% coal tar topical solution (Liquor Carbonis Detargos) equivalent to 2% coal tar.</p>	<p>NDC 67857-801-52 Psoriasis Foam</p>	<p>Drug Facts (continued)</p> <p>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.</p> <p>Directions</p> <ul style="list-style-type: none"> 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. <p>Other information</p> <ul style="list-style-type: none"> contents under pressure. Do not puncture or incinerate. store at 89-77°F (30-25°C) do not expose to heat or store at temperatures above 130°F (48°C). <p>Inactive ingredients</p> <p>Caprylsyngic triglyceride, cetearyl 20, citric acid, cyclomethicone, dimethicone, EDTA disodium, glycerin, hydroxyethyl methyl cellulose, isopropyl myristate, peppermint oil, phenylethanol, potassium sorbate, purified water, sodium citrate, stearic acid, xanthan gum, hydrocarbon (propane/butane) propellant.</p> <p>Questions ? 1-800-866-6786</p>
<p>Drug Facts</p> <p>Active Ingredient Purpose</p> <p>Coal Tar 2% Psoriasis (From Coal Tar Topical Solution USP, 10%)</p> <p>Use for relief of the symptoms of psoriasis</p> <p>Warnings For external use only</p> <p>Flammable Avoid fire, flame, or smoking during and immediately following application.</p> <p>Do not use</p> <ul style="list-style-type: none"> 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 <p>Ask a doctor before use if you have a condition that covers a large area of the body.</p> <p>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.</p> <p>When using this product</p> <ul style="list-style-type: none"> 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. <p>Stop use and ask doctor if condition worsens or does not improve after regular use of this product as directed.</p>		<p>Patent Pending Made in USA Marketed by: Promius Pharma, LLC Bridgeport, NJ 08007 Under license from Foamix LTD, Israel</p> <p>021825 1 0722 12803-0728</p> 
<p>PROMIUS PHARMA NET WT. 3.3 oz (100 g)</p>		

Carton (California)

NDC 67857-801-26

Psoriasis Foam

Scytera™
(Coal Tar) Foam 2%

Promius Pharma™
NET WT. 3.3 oz (100 g)



Scytera™ (Coal Tar)Foam 2%, 12 g Sample Size Packer (Box)

Available in 100 g Cans

**Scytera™
(Coal Tar) Foam 2%**

Promius Pharma™

Professional Samples

Net Quantity 12 x 12 g Cans
NDC 67857-801-12



Packer (Box) (California)

Available in 100 g Cans

Scytera™
(Coal Tar) Foam 2%
Promius Pharma™

Professional Samples

Net Quantity 12 x 12 g Cans
NDC 67857-801-19

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COAL TAR (UNII: R533ESO2EC) (COAL TAR - UNII:R533ESO2EC)	COAL TAR	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE (UNII: 3NXW29V3WO)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PEPPERMINT OIL (UNII: AV092KU4JH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63094-0801-1	1 in 1 CARTON		
1		100 g in 1 CAN		
2	NDC:63094-0801-2	12 in 1 BOX		
2		12 g in 1 CAN		
3	NDC:63094-0801-3	1 in 1 CARTON		
3	NDC:63094-0801-1	100 g in 1 CAN		
4	NDC:63094-0801-4	12 in 1 BOX		
4	NDC:63094-0801-2	12 g in 1 CAN		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358	10/31/2008	

Labeler - DPT Laboratories, Ltd. (621782218)

Revised: 8/2009

DPT Laboratories, Ltd.