

DENOREX THERAPEUTIC- coal tar and menthol shampoo
Neoteric Cosmetics, Inc.

Denorex Therapeutic

Drug Facts

Active Ingredients:

Coal tar solution 9.0% v/v (equivalent to 1.8% coal tar)

Purpose:

Controls the symptoms of dandruff, seborrheic dermatitis and psoriasis

Active Ingredients:

Menthol 1.5%

Purpose:

Controls scalp itch

Uses:

- relieves and helps stop the recurrence of scalp itching, irritation, redness, flaking and scaling associated with dandruff, seborrheic dermatitis and psoriasis
- extra relief of itching due to dandruff

Warnings:

For external use only

Do not use:

- for prolonged periods without consulting a doctor
- this product with other forms of psoriasis therapy such as ultraviolet radiation or prescription drugs unless directed to do so by a doctor

Ask a doctor before use if you have

condition covers a large area of the body.

When using this product:

- avoid contact with the eyes. If contact occurs, rinse thoroughly with water.
- use caution in exposing skin to sunlight after applying. It may increase your tendency to sunburn for up to 24 hours after application.

Stop use and ask a doctor if:

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

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

- shake well
- apply to wet hair
- gently massage into hair and scalp to work up a lather
- rinse thoroughly and repeat
- for best results, use at least twice a week or as directed by a doctor

Inactive ingredients

alcohol 7.3%, avocado oil, chloroxylenol, citric acid, dimethicone copolyol, FD&C red #40, fragrance, glycol distearate, hydroxypropyl methylcellulose, lauramide DEA, panthenol (provitamin B5), PEG-30 lanolin, quaternium-80, ricinoleamidopropyl ethyldimonium ethosulfate, TEA lauryl sulfate, vitamin E acetate, water

Questions?

1-800-443-4908 or www.denoraxshampoo.com

WARNING:

This product contains a chemical known to the State of California to cause cancer.

PRINCIPAL DISPLAY PANEL



THERAPEUTIC Denorex

1.8% COAL TAR; 1.5% MENTHOL
MAXIMUM ITCH RELIEF

DANDRUFF SHAMPOO
+ CONDITIONER

With
MENTARTM
1.8% COAL TAR; 1.5% MENTHOL

**Maximum Strength
For Persistent Itching**

Helps control dandruff, seborrheic dermatitis & psoriasis
Relieves scalp irritation & itching with menthol
Conditions & moisturizes

**“The Tingle
Tells You It’s Working”**

10 FL OZ (296 mL)

THERAPEUTIC Denorex DANDRUFF SHAMPOO + CONDITIONER MAXIMUM ITCH RELIEF

- Contains dual action formula of 1.8% coal tar and 1.5% menthol to provide maximum relief of stubborn scalp itch
- Vitamin-enriched for healthy, good-looking hair
- Built-in conditioners provide the body and shine you would expect from a separate conditioner

Drug Facts

Active Ingredients:	Purpose:
Coal tar solution 9.0% w/v.....	Controls the symptoms of dandruff, seborrheic dermatitis and psoriasis (equivalent to 1.8% w/w coal tar)
Menthol 1.5%.....	Controls scalp itch

Uses: • Relieves and helps stop the recurrence of itching, irritation, redness, flaking and scaling associated with dandruff, seborrheic dermatitis and psoriasis • Extra relief of itching due to dandruff.

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Directions: • Shake well • Apply to wet hair • Gently massage into hair and scalp to work up a lather • Rinse thoroughly and repeat • For best results, use at least twice weekly or as directed by a doctor.

Other information: Store at 20-25° C (68-77° F)

Inactive ingredients: TEA lauryl sulfate, water, lauramide DEA, PEG-30 lanolin, panthenol (provitamin B5), glycol distearate, fragrance, hydroxypropyl methylcellulose, vitamin E acetate, avocado oil, chloroxylenol, FD&C Red No. 40, citric acid, ricinoleamidopropyl ethyldimonium ethosulfate, dimethicone copolyol, quaternium-80

Questions? 1-800-552-5742 or denorex.com

WARNING: Cancer – www.P65Warnings.ca.gov

Manufactured for Nestec Cosmetics, Inc.
Greenwood Village, CO 80111 USA

THERAPEUTIC
Denorex
MAXIMUM ITCH RELIEF

DANDRUFF SHAMPOO
+ CONDITIONER

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Uses: • Relieves and helps stop the recurrence of itching, irritation, redness, flaking and scaling associated with dandruff, seborrheic dermatitis and psoriasis • Extra relief of itching due to dandruff.

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THERAPEUTIC
Denorex

1.8% COAL TAR; 1.5% MENTHOL

MAXIMUM ITCH RELIEF

DANDRUFF SHAMPOO
+ CONDITIONER

With
MENTAR™
1.8% COAL TAR; 1.5% MENTHOL

**Maximum Strength
For Persistent Itching**

Denorex® Maximum Itch Relief contains menthol to soothe scalp irritation.

Helps control dandruff, seborrheic dermatitis & psoriasis

Relieves scalp irritation & itching with menthol

Denorex® Maximum Itch Relief contains a dual action formula for maximum relief of stubborn scalp itch.

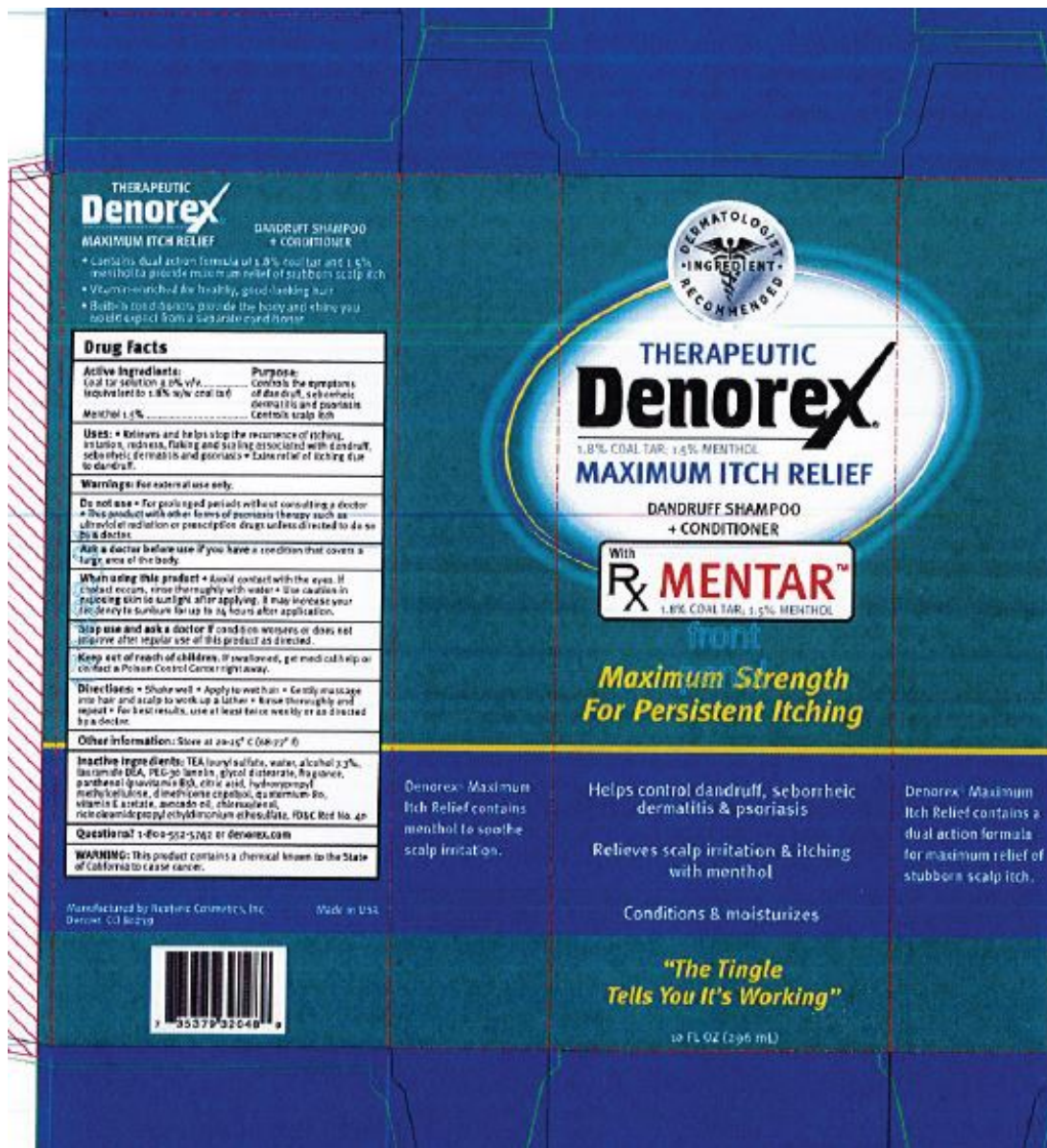
Conditions & moisturizes

**“The Tingle
Tells You It’s Working”**

10 FL. OZ. (296 mL)



Manufactured for Neoteric Cosmetics, Inc.
Greenwood Village, CO 80111



THERAPEUTIC

Denorex

1.8 % Coal Tar; 1.5 % Menthol

Maximum Itch Relief

DANDRUFF

S HAMPOO +

CONDITIONER

10 FL OZ (296 mL)

THERAPEUTIC
Denorex
MAXIMUM ITCH RELIEF

DANDRUFF SHAMPOO
+ CONDITIONER

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Drug Facts

Active Ingredients: **Purpose:**
Coal tar solution 9.0% v/v.....Controls the symptoms of dandruff, (equivalent to 1.8% w/w coal tar) ..seborrheic dermatitis and psoriasis
Menthol 1.5%Controls scalp itch

Uses: • Relieves and helps stop the recurrence of itching, irritation, redness, flaking and scaling associated with dandruff, seborrheic dermatitis and psoriasis • extra relief of itching due to dandruff

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Questions? 1-800-220-0151 or www.denorexshampoo.com

WARNING: This product contains a chemical known to the State of California to cause cancer.

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Plymouth Meeting, PA 19462

Made in USA
DN32048



NDC 51545-220-12



THERAPEUTIC
Denorex
1.8% COAL TAR; 1.5% MENTHOL
MAXIMUM ITCH RELIEF

DANDRUFF SHAMPOO
+ CONDITIONER

**Maximum Strength
for Persistent Itching**

Denorex® Maximum Itch Relief contains menthol to soothe scalp irritation!
"The tingle tells you it's working."

- Helps control severe dandruff symptoms
- Extra ingredient for stubborn scalp itch
- Conditioner moisturizes for healthy hair

Denorex® Maximum Itch Relief contains a dual action formula for maximum relief of stubborn scalp itch.
"The tingle tells you it's working."

**"The Tingle
Tells You it's Working."**

10 FL OZ (296 mL)

DENOREX THERAPEUTIC

coal tar and menthol shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62673-174
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COAL TAR (UNII: R533ES02EC) (COAL TAR - UNII:R533ES02EC)	COAL TAR	0.018 g in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.015 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
CHLOROXYLENOL (UNII: 0F32U78V2Q)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LAURIC DIETHANOLAMIDE (UNII: I29I2VHG38)	
PANTHENOL (UNII: WW9CM0O67Z)	
RICINOLEAMIDOPROPYL ETHYLDIMONIUM ETHOSULFATE (UNII: V176GWC2SR)	
TRIETHANOLAMINE LAURYL SULFATE (UNII: E8458C1KAA)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62673-174-10	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/13/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M032	12/13/2017	

Labeler - Neoteric Cosmetics, Inc. (790615181)

Registrant - Pharma Nobis, LLC (118564114)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	manufacture(62673-174) , analysis(62673-174) , pack(62673-174) , label(62673-174)

Revised: 12/2023

Neoteric Cosmetics, Inc.