

DENOREX THERAPEUTIC- coal tar and menthol shampoo
Ultimark Products LLC

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.

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

S HAMPOO +

CONDITIONER

10 FL OZ (296 mL)

THERAPEUTIC
Denorex
MAXIMUM ITCH RELIEF

DANDRUFF SHAMPOO
+ CONDITIONER

- 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% 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

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 a condition that 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 weekly or as directed by a doctor

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

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

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

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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:51545-220
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COAL TAR (UNII: R533ESO2EC) (COAL TAR - UNII:R533ESO2EC)	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: WV9CM0O67Z)	
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:51545-220-12	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	09/09/2019	

Labeler - Ultimark Products LLC (964734078)

Registrant - Humco Holding Group, Inc. (825672884)

Establishment

Name	Address	ID/FEI	Business Operations
Humco Holding Group, Inc.		825672884	analysis(51545-220) , manufacture(51545-220) , pack(51545-220) , label(51545-220)

Revised: 9/2019

Ultimark Products LLC