

## **DENOREX EXTRA STRENGTH- salicylic acid shampoo**

**Humco Holding Group, 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.*

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### **Denorex Extra Strength**

#### **Drug Facts**

##### ***Active Ingredients:***

Salicylic acid 3%

##### ***Purpose***

Controls the symptoms of dandruff, seborrheic dermatitis and psoriasis

##### ***Uses***

- Reduces and helps eliminate scalp itching, flaking and scaling associated with dandruff, seborrheic dermatitis and psoriasis
- Helps prevent recurrence of the symptoms of dandruff, seborrheic dermatitis and psoriasis

##### ***Warnings***

**For external use only.**

**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 eyes thoroughly with water.

##### **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

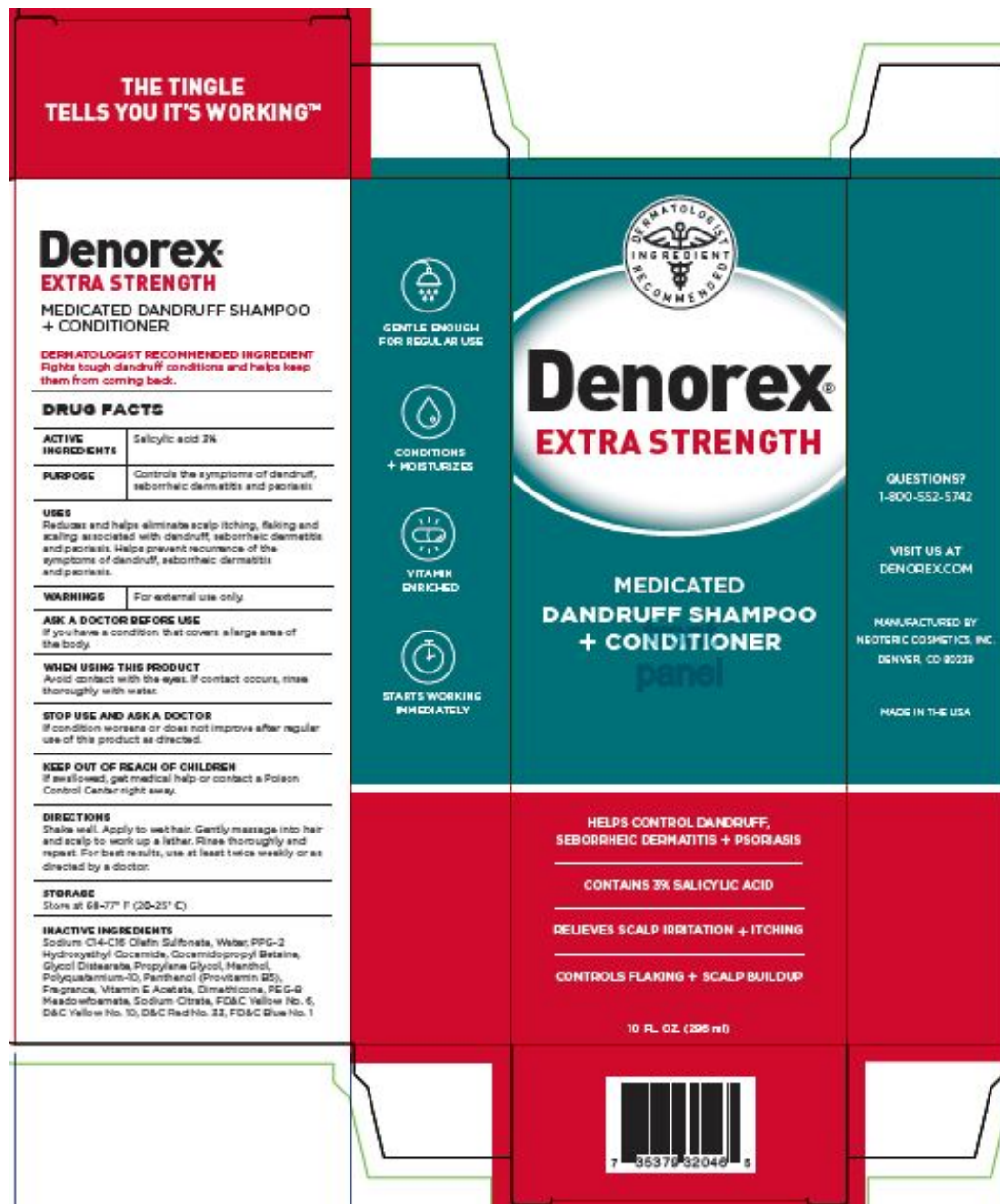
cocamidopropyl betaine, D&C Red No. 33, D&C Yellow No. 10, dimethicone PEG-8 meadowfoamate, FD&C Blue No. 1, FD&C Yellow No. 6, fragrance, glycol distearate, menthol, panthenol, polyquaternium-10, PPG-2 hydroxyethyl cocamide, propylene glycol, sodium C14-C16 olefin sulfonate, sodium citrate, vitamin E acetate, water

## Questions?

1-800-220-0151

www.denorex.net

## PRINCIPAL DISPLAY PANEL



**EXTRA STRENGTH**  
**Denorex**  
**DANDRUFF CONTROL**

DANDRUFF SHAMPOO  
+ CONDITIONER

- Contains 3% Salicylic acid to help control the symptoms of dandruff, seborrheic dermatitis and psoriasis
- Vitamin-enriched for healthy, good-looking hair
- Built-in conditioners provide the body and shine you would expect from a separate conditioner

**Drug Facts**

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Salicylic acid 3% .....Controls the symptoms of dandruff, seborrheic dermatitis and psoriasis

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cocamidopropyl betaine, D&C Red No.33, D&C Yellow No.10, dimethicone PEG-8 meadowfoamate, FD&C Blue No.1, FD&C Yellow No.6, fragrance, glycol distearate, menthol, panthenol, polyquaternium-10, PPG-2 hydroxyethyl cocamide, propylene glycol, sodium c14-c16 olefin sulfonate, sodium citrate, vitamin E acetate, water

**Questions?**

1-800-220-0151 or [www.denorexshampoo.com](http://www.denorexshampoo.com)

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Made in USA  
DN32046



**EXTRA STRENGTH**  
**Denorex**

3% SALICYLIC ACID

**DANDRUFF CONTROL**

DANDRUFF SHAMPOO  
+ CONDITIONER

**Controls Flaking  
& Scalp Build-Up**

Denorex® Dandruff Control fights all tough dandruff conditions and is gentle enough for everyday use.  
"The tingle tells you it's working."

- Helps controls dandruff, seborrheic dermatitis & psoriasis
- Relieves scalp irritation, itching & scalp build up
- Conditioner moisturizes for healthy hair

Denorex® Dandruff Control fights all tough dandruff conditions and helps keep them from coming back.  
"The tingle tells you it's working."

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

10 FL OZ (296 mL)

## DENOREX EXTRA STRENGTH

salicylic acid shampoo

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0395-0059
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	0.03 g in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	

<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>GLYCOL DISTEARATE</b> (UNII: 13W7MDN21W)	
<b>MENTHOL</b> (UNII: L7T10EP3A)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>PANTHENOL</b> (UNII: WV9CM0O67Z)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0395-0059-10	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/17/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	06/17/2019	

**Labeler** - Humco Holding Group, Inc. (825672884)

**Registrant** - Humco Holding Group, Inc. (825672884)

### Establishment

Name	Address	ID/FEI	Business Operations
Humco Holding Group, Inc.		825672884	manufacture(0395-0059) , analysis(0395-0059) , pack(0395-0059) , label(0395-0059)

Revised: 6/2020

Humco Holding Group, Inc.