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.

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 20º-25º C (68º – 77º F)

Inactive ingredients

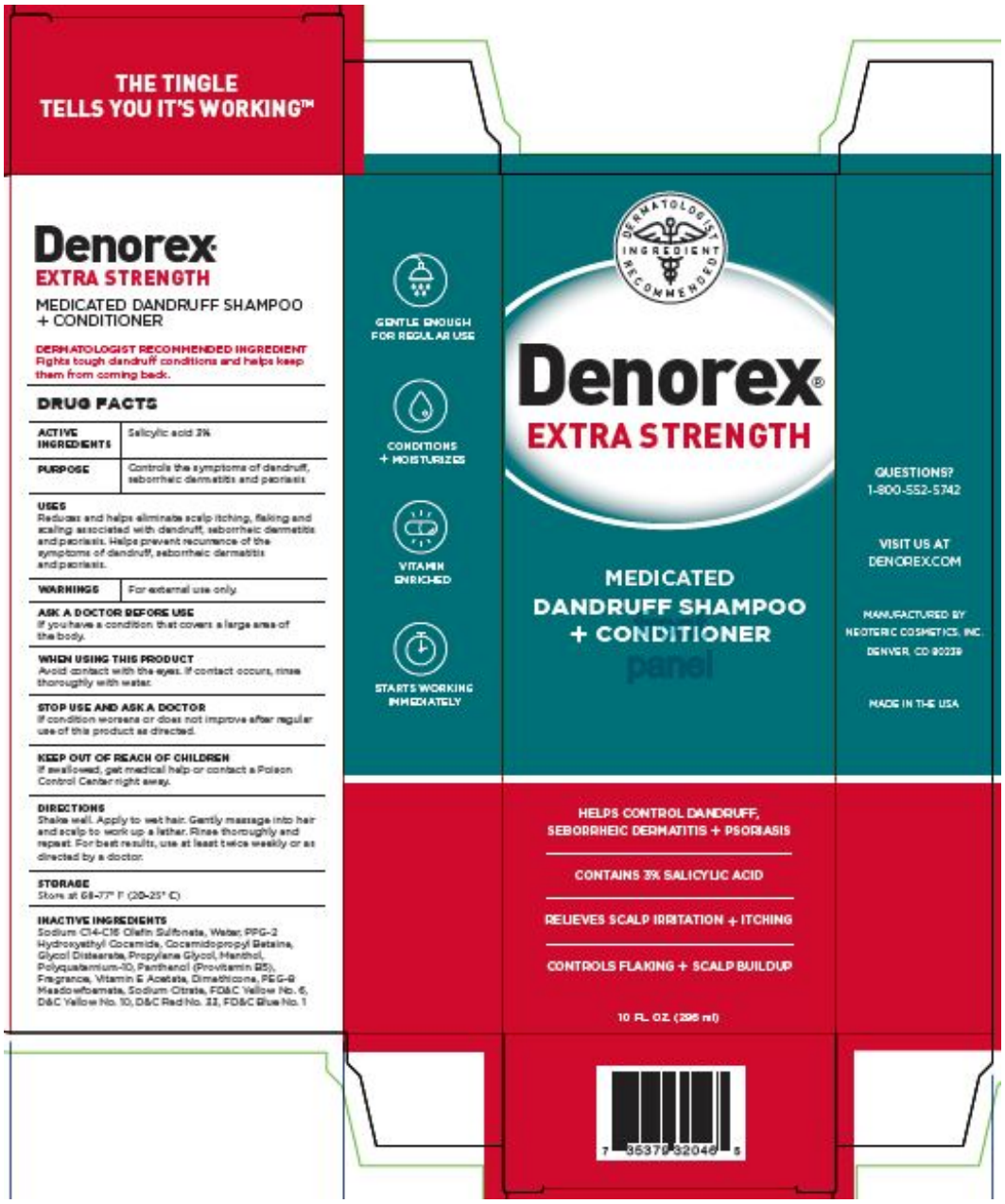
cocamidopropyl betaine, D&C Red No. 33, D&C Yellow No. 10, dimethicone PEG-8 meadowfoamate, FD&C Blue No. 1, FD&C Yellow No. 6, fragrance, glycol distearate, menthol, panthenol, polyquaternium-10, PPG-2 hydroxyethyl cocamide, propylene glycol, sodium C14-C16 olefin sulfonate, sodium citrate, vitamin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

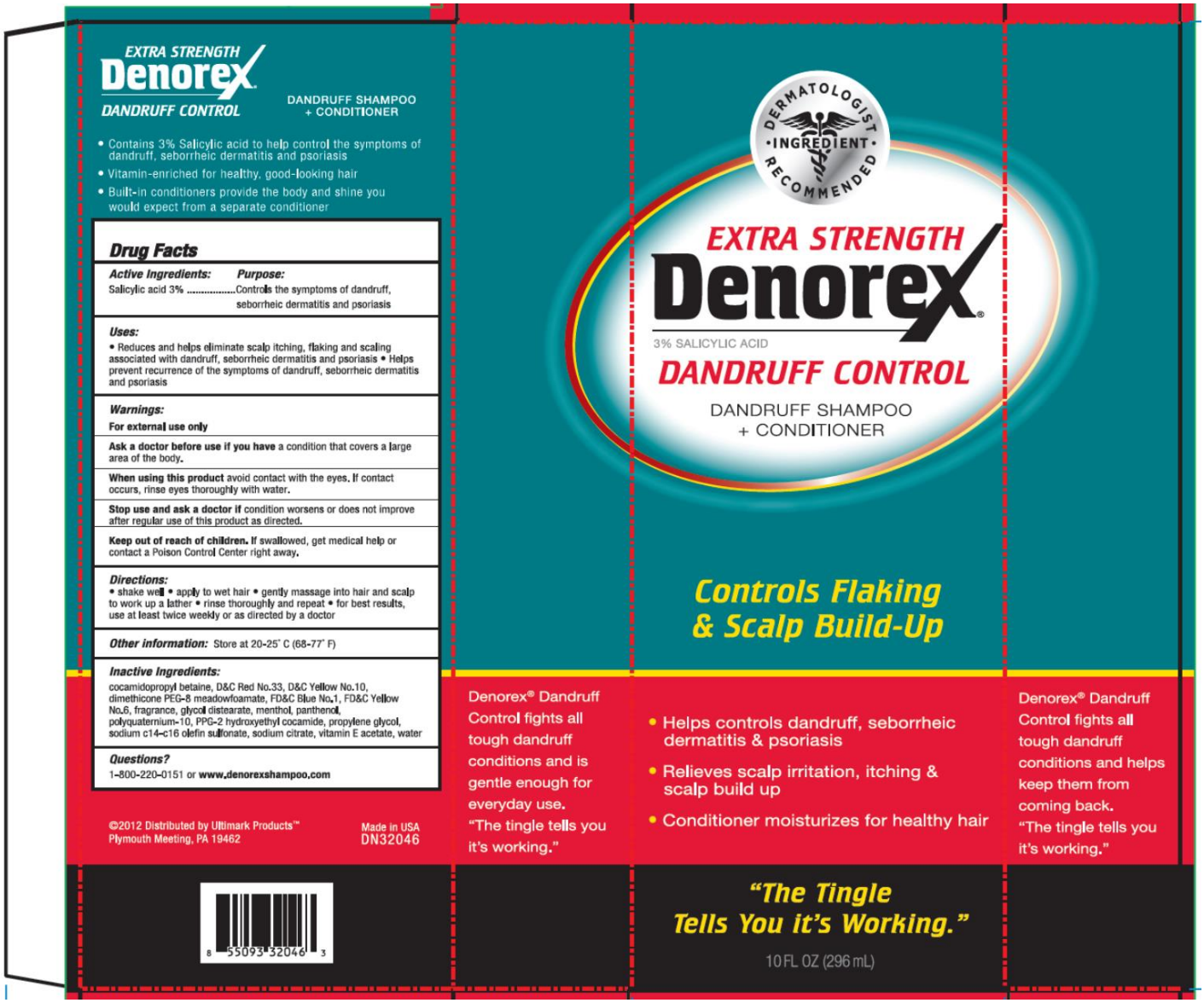
Questions?

1-800-220-0151

www.denorex.net

PRINCIPAL DISPLAY PANEL





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: 059QF0KO0R)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
MENTHOL (UNII: L7T10EIP3A)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
PANTHENOL (UNII: WV9CM0O67Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (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.