THERASEAL- dimethicone cream
Bausch Health US, 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.

TheraSeal Hand Protection

Drug Facts

Active Ingredient

Dimethicone 1% w/w

Purpose

Skin Protectant

Uses

Helps prevent and temporarily protect chafed, chapped, cracked, dry skin.

Warnings

For external use only.

When using this product avoid contact with eyes.

Not to be applied over deep or puncture wounds, infections or lacerations. If condition worsens or does not improve within 7 days, consult a physician.

Keep out of reach of children.

Directions

Apply liberally as often as necessary.

Inactive Ingredients

Purified water, cyclomethicone, cyclomethicone aluminum magnesium hydroxide stearate, cetyl dimethicone copolyol and polyglyceryl-4-isostearate and hexyl laurate, sodium chloride, imidurea.

Questions?

1-866-819-9007
www.CoriaLabs.com

U.S. Patent 5482714

Distributed by: Coria Laboratories, a division of Valeant Pharmaceuticals, North America, Fort Worth, TX 76107

Manufactured by: DPT Laboratories, Ltd., San Antonio, Texas 78215

106022-0410

PRINCIPAL DISPLAY PANEL - 6 ounce label

PROTECTS DAMAGED HANDS

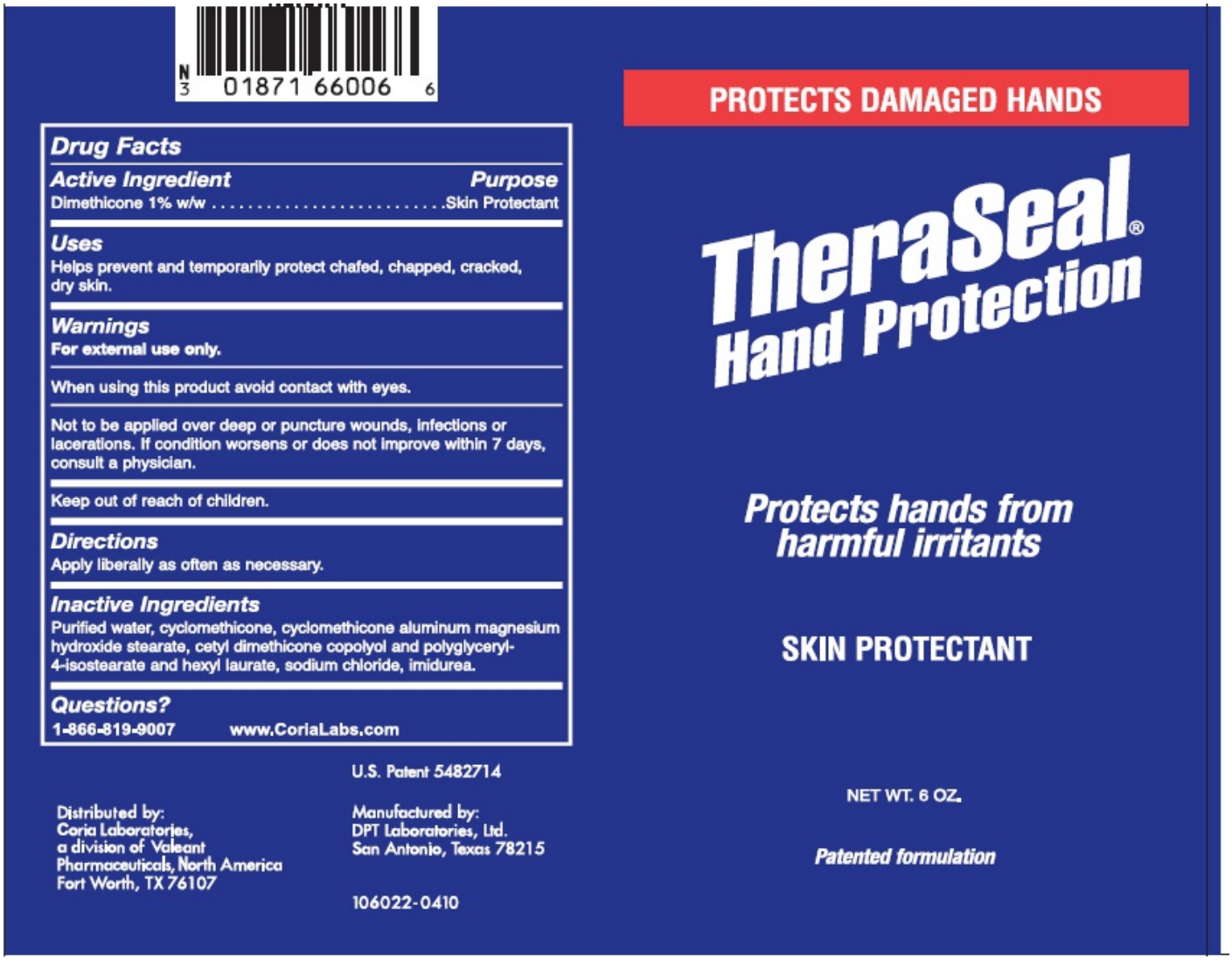
TheraSeal®
Hand Protection

Protects hands from
harmful irritants

SKIN PROTECTANT

NET WT. 6 OZ.

Patented formulation



THERASEAL

dimethicone cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0187-1660
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Dimethicone (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	1.7 g in 170.10 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	
Cyclomethicone (UNII: NMQ347994Z)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	

Hexyl Laurate (UNII: 4CG9F9W01Q)	
Sodium Chloride (UNII: 451W47IQ8X)	
Imidurea (UNII: M629807ATL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0187-1660-06	1 in 1 CARTON	01/01/2012	
1		170.10 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/01/2012	

Labeler - Bausch Health US, LLC (831922468)

Establishment

Name	Address	ID/FEI	Business Operations
DPT Laboratories, Ltd.		832224690	MANUFACTURE(0187-1660)

Revised: 2/2015 Bausch Health US, LLC