DERMA BRITE SPF 35- octinoxate, octisalate, oxybenzone cream
PHARMAGEL INTERNATIONAL INC

PHARMAGEL - DERMA BRITE (67879-308)

ACTIVE INGREDIENTS

Octinoxate 7.5%

Octisalate 5.0%

Oxybenzone 3.0%

PURPOSE

Sunscreen

USES

- helps prevent sunburn
- if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

WARNINGS

For external use only.

Do not use on damaged or broken skin.

When using product keep out of eyes. Rinse with warm water to remove.

Stop use and ask doctor if rash occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS

• apply liberally 15 minutes before sun exposure

• reapply:
• after 40 minutes of swimming or sweating.

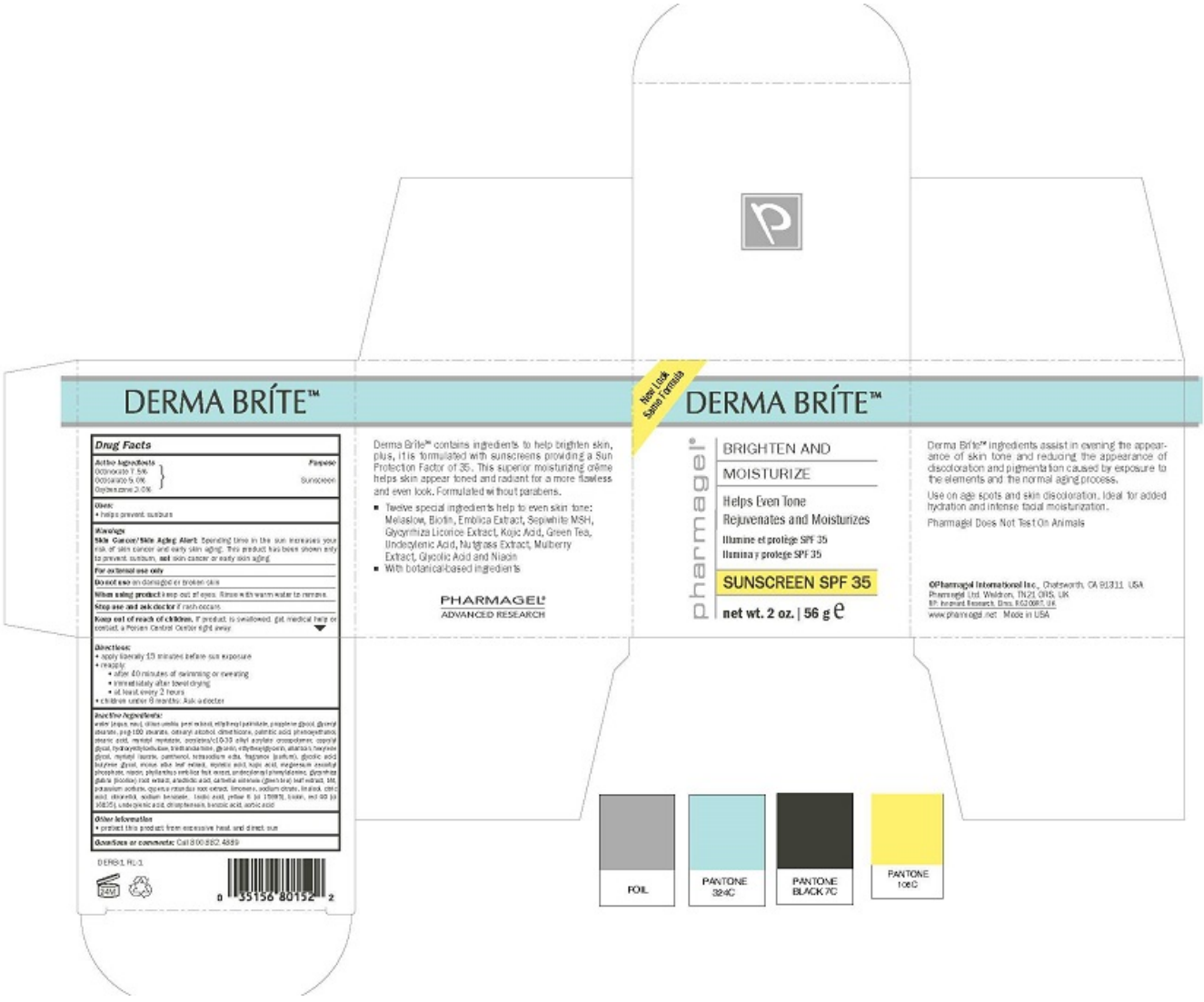
• immediately after towel drying
• at least every 2 hours

• Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
• limit time in the sun, especially from 10 a.m. - 2 p.m.
• wear long-sleeve shirts, pants, hats and sunglasses

• children under 6 months: Ask a doctor

INACTIVE INGREDIENTS:

water (aqua, eau), citrus unshiu peel extract, ethylhexyl palmitate, propylene glycol, glyceryl stearate, peg-100 stearate, cetearyl alcohol, dimethicone, palmitic acid, phenoxyethanol, stearic acid, myristyl myristate, acrylates/c10-30 alkyl acrylate crosspolymer, caprylyl glycol, hydroxyethylcellulose, triethanolamine, glycerin, ethylhexylglycerin, allantoin, hexylene glycol, myristyl laurate, panthenol, tetrasodium edta, fragrance (parfum), glycolic acid, butylene glycol, morus alba leaf extract, myristic acid, kojic acid, magnesium ascorbyl phosphate, niacin, phyllanthus emblica fruit exract, undecylenoyl phenylalanine, glycyrrhiza glabra (licorice) root extract, arachidic acid, camellia sinensis (green tea) leaf extract, bht, potassium sorbate, cyperus rotundus root extract, limonene, sodium citrate, linalool, citric acid, citronellol, sodium benzoate, lactic acid, yellow 6 (ci 15985), biotin, red 40 (ci 16035), undecylenic acid, chlorphenesin, benzoic acid, sorbic acid



DERMA BRITE SPF 35
octinoxate, octisalate, oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67879-308
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
TANGERINE PEEL (UNII: JU3D414057)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PALMITIC ACID (UNII: 2V16EO95H1)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ALLANTOIN (UNII: 344S277G0Z)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
MYRISTYL LAURATE (UNII: 58U0NZN2BT)	
PANTHENOL (UNII: WV9CM0O67Z)	
EDETATE SODIUM (UNII: MP1J8420LU)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
MORUS ALBA LEAF (UNII: M8YIA49Q2P)	
MYRISTIC ACID (UNII: 0I3V7S25AW)	
KOJIC ACID (UNII: 6K23F1TT52)	
MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5)	
NIACIN (UNII: 2679MF687A)	
PHYLLANTHUS EMBLICA FRUIT (UNII: YLX4CW2576)	
UNDECYLENOYL PHENYLALANINE (UNII: 271P08C6OD)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
ARACHIDIC ACID (UNII: PQB8MJD4RB)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	

BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CYPERUS ROTUNDUS ROOT (UNII: 4B51SRR959)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
LINALOOL, (+)- (UNII: F4VNO44C09)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
.BETA.-CITRONELLOL, (+/-)- (UNII: 565OK72VNF)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
LACTIC ACID (UNII: 33X04XA5AT)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
BIOTIN (UNII: 6SO6U10H04)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
UNDECYLENIC ACID (UNII: K3D86KJ24N)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SORBIC ACID (UNII: X045WJ989B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67879-308-51	1 in 1 BOX	06/13/2016	
1	NDC:67879-308-11	56 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/18/2015	

Labeler - PHARMAGEL INTERNATIONAL INC (603215182)

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