

DERMA FADE- octinoxate, octisalate, oxybenzone cream
PHARMAGEL INTERNATIONAL 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.

ACTIVE INGREDIENTS

Octinoxate 7.5%

Octisalate 5.0%

Oxybenzone 3.0%

PURPOSE

Sunscreen

USES

Lightens the appearance of age spots & skin discoloration. Provides moderate protections against sunburn.

WARNINGS

Warnings using this product – For external use only. Avoid contact with eyes. If product gets into the eyes, rinse thoroughly with water. Do not use on children under 12 years of age unless directed by a doctor. Stop use & consult a doctor if rash or irritation develops and persists.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

DIRECTIONS

Apply to age spots and skin discoloration. Can be used as a full face moisturizing treatment and sunscreen before sun exposure.

INACTIVE INGREDIENTS:

ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, ALLANTOIN, BIOTIN, BUTYLENE GLYCOL, CAMELLIA SINENSIS (GREEN TEA) LEAF EXTRACT, CAPRYLYL GLYCOL, CETEARYL ALCOHOL, CITRIC ACID, CITRUS UNSHIU PEEL EXTRACT, CYPERUS ROTUNDUS ROOT EXTRACT, DIMETHICONE, DISODIUM EDTA, ETHYLHEXYL PALMITATE, ETHYLHEXYLGLYCERIN, FRAGRANCE (PARFUM), GLYCERIN, GLYCERYL STEARATE, GLYCOLIC ACID, GLYCYRRHIZA GLABRA (LICORICE) ROOT EXTRACT, HEXYLENE GLYCOL, HYDROXYETHYLCELLULOSE, KOJIC ACID, LACTIC ACID, MAGNESIUM ASCORBYL PHOSPHATE, MORUS ALBA LEAF EXTRACT, MYRISTYL LAURATE, MYRISTYL MYRISTATE, NIACIN, PANTHENOL, PEG-100 STEARATE, PHENOXYETHANOL, PHYLLANTHUS EMBLICA FRUIT EXTRACT, PROPYLENE GLYCOL, RED 40 (CI 16035), SODIUM CITRATE, STEARIC ACID, TETRASODIUM EDTA, TRIETHANOLAMINE, UNDECYLENIC ACID, UNDECYLENOYL PHENYLALANINE, WATER (AQUA), YELLOW 6 (CI 15985)

Derma Fade® contains powerful antioxidants known for their skin rejuvenating and fading properties. Derma Fade is a superior moisturizing crème with powerful skin lighteners and SPF 35 that fades age spots and skin discoloration for a more even, flawless skin tone. Paraben Free.

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www.pharmagel.net Made in USA DER-1 Rev 2

DERMA FADE®

LIGHTENING AND FADING

Evens Skin Tone, Rejuvenates and Moisturizes
Crème éclaircissante et estompanante Crema ad

ALL SKIN TYPES | WITH SPF

56 g e 2 oz.

DERMA FADE

octinoxate, octisalate, oxybenzone cream

Product Information

| | | | |
|--------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:67879-301 |
|--------------|----------------|--------------------|---------------|

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 | 5.0 g in 100 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE | 3.0 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO) | |
| ALLANTOIN (UNII: 344S277G0Z) | |
| BIOTIN (UNII: 6SO6U10H04) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| TANGERINE PEEL (UNII: JU3D414057) | |
| CYPERUS ROTUNDUS TUBER (UNII: 4B51SRR959) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| ETHYLHEXYL PALMITATE (UNII: 2865993309) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| GLYCOLIC ACID (UNII: 0WT12SX38S) | |
| GLYCYRRHIZA GLABRA (UNII: 2788Z9758H) | |
| HEXYLENE GLYCOL (UNII: KEH0A3F75J) | |
| HYDROXYETHYL CELLULOSE (3000 MPAS AT 1%) (UNII: 7Q6P4JN1QT) | |
| KOJIC ACID (UNII: 6K23F1TT52) | |
| LACTIC ACID (UNII: 33X04XA5AT) | |
| MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5) | |
| MORUS ALBA LEAF (UNII: M8YIA49Q2P) | |
| MYRISTYL LAURATE (UNII: 58U0NZN2BT) | |
| MYRISTYL MYRISTATE (UNII: 4042ZC00DY) | |
| NIACIN (UNII: 2679MF687A) | |
| PANTHENOL (UNII: WV9CM0067Z) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| PHYLLANTHUS EMBLICA FRUIT (UNII: YLX4CW2576) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| EDETATE SODIUM (UNII: MP1J8420LU) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |

| | |
|---|--|
| UNDECYLENIC ACID (UNII: K3D86KJ24N) | |
| UNDECYLENOYL GLYCINE (UNII: 4D20464K2J) | |
| WATER (UNII: 059QF0KO0R) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:67879-301-51 | 1 in 1 BOX | 06/18/2015 | |
| 1 | NDC:67879-301-11 | 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 not final | part352 | 06/18/2015 | |

Labeler - PHARMAGEL INTERNATIONAL INC (603215182)

Registrant - PHARMAGEL INTERNATIONAL INC (603215182)

Revised: 11/2018

PHARMAGEL INTERNATIONAL INC