

DERMASHIELD- titanium dioxide, octinoxate cream cream
USRX 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.

DermaShield SPF 30

PRO STRENGTH
By URBAN SKIN RX®

OIL CONTROL
DERMASHIELD
MATTIFYING MOISTURIZER

BROAD SPECTRUM SUNSCREEN
ALL DAY SUN PROTECTION
SPF 30

3 fl oz / 90 mL

Drug Facts

Active Ingredients: Titanium Dioxide 2% Octinoxate 7%	Purpose Sunscreen
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Uses
Help 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 this product keep out of eyes. Rinse with water to remove. Stop use and ask a 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 to all skin exposed to the sun.
- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply after 40 minutes of swimming or sweating, immediately after towel drying and at least every 2 hours.
- For children under 6 months of age: Ask a doctor.

Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value 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-sleeved shirts, pants, hats, and sunglasses.

Inactive Ingredients:
ISOCETYL STEARATE, SORBITOL, CETEARYL ALCOHOL, CETEARETH-20, TOCOPHERYL ACETATE, ACETYL HEXAPEPTIDE-8, HYDROLYZED RICE PROTEIN, ALCOHOL SDA-40, DIMETHICONE, OCTYL SALICYLATE, CETYL ALCOHOL, METHICONE, SODIUM LAURETH SULFATE, CARBOMER, CAMELLIA SINENSIS (GREEN TEA) LEAF EXTRACT, FRAGRANCE, TRIETHANOLAMINE, STEARIC ACID, LECITHIN, ALUMINA, CAPRYLYL GLYCOL, METHYLSOETHAZOLINONE.

Other information: Protect the product in this container from excessive heat and direct sun.

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ACTIVE INGREDIENT:

- TITANIUM DIOXIDE 2%
- OCTINOXATE 7%

Sunscreen

FOR EXTERNAL USE ONLY

DO NOT USE - On damaged or broken skin

STOP USE AND ASK A DOCTOR IF A RASH OCCURRS

INACTIVE INGREDIENTS:

DERMASHIELD

titanium dioxide, octinoxate cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70809-1901
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 mg in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LM26O6933)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
SORBITOL (UNII: 506T60A25R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ISOCETYL STEARATE (UNII: 3RJ7186O9W)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
OCTISALATE (UNII: 4X49Y0596W)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ACETYL HEXAPEPTIDE-8 (UNII: L4EL31FWIL)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70809-1901-1	90 mL in 1 TUBE; Type 0: Not a Combination Product	07/08/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/08/2019	

Labeler - USRX LLC (115270633)**Registrant** - USRX LLC (115270633)

Revised: 9/2019

USRX LLC