

DEUX DERME - AGE AND DARK SPOT PREVENTION- octinoxate and titanium dioxide lotion

Cosmetic Solutions 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.

Deux Derme - Age & Dark Spot Prevention

DRUG FACTS

ACTIVE INGREDIENTS

Titanium Dioxide 2.5%, Octinoxate 7%.

Purpose

Sunscreen

USES

Help prevent sunburn.

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

Water (Aqua), Aloe Barbadensis Leaf Extract, Isocetyl Stearate, Sorbitol, Cetearyl Alcohol, Cetareth-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, Methylisothiazolinone.

OTHER INFORMATION

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

PRINCIPAL DISPLAY PANEL - 60 ml Bottle Label

DEUX + DERMÈ

AGE & DARK SPOT
PREVENTION


SpotActive-xl™ and SPF30 Broad Spectrum
Sunscreen

Daily Advanced Cream Concentrate Formula
for Age & Dark Spots

A scientific formula to protect against both
UVA and UVB radiation and reduce the
appearance of age spots

CRUELTY-FREE & VEGAN

2.0 fl.oz / 60ml

	<h3>AGE & DARK SPOT PREVENTION</h3>	DRUG FACTS: ACTIVE INGREDIENTS: Titanium Dioxide 2.5%, Octinoxate 7%. } Sunscreen Purpose USES: Help prevent sunburn. 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: Water (Aqua), Aloe Barbadensis Leaf Extract, 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, Methylisothiazolinone. OTHER INFORMATION: Protect the product in this container from excessive heat and direct sun.	
	<p>SpotActive-xl™ and SPF30 Broad Spectrum Sunscreen</p> <p>Daily Advanced Cream Concentrate Formula for Age & Dark Spots</p> <p>Formule de Crème Concentré Quotidienne Pour Les Taches de Vieillesse</p> <p>A scientific formula to protect against both UVA and UVB radiation and reduce the appearance of age spots</p> <p style="text-align: center;">CRUELTY-FREE & VEGAN 2.0 fl.oz / 60ml</p> <p style="text-align: center;">  www.DeuxDerme.com Manufactured in the USA for Splügen Moritz LLC Las Vegas, NV 89120  </p>		

DEUX DERME - AGE AND DARK SPOT PREVENTION

octinoxate and titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66163-6503
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	70 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Isocetyl Stearate (UNII: 3RJ7186O9W)	
Sorbitol (UNII: 506T60A25R)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Polyoxyl 20 Cetostearyl Ether (UNII: YRC528SWUY)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Acetyl Hexapeptide-8 (UNII: L4EL31FWIL)	
Dimethicone (UNII: 92RU3N3Y1O)	
Octisalate (UNII: 4X49Y0596W)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Methicone (20 Cst) (UNII: 6777U11MKT)	
Sodium Laureth-3 Sulfate (UNII: BPV390UAP0)	
Carboxypolymethylene (UNII: 0A5MM307FC)	
Green Tea Leaf (UNII: W2ZU1RY8B0)	
Trolamine (UNII: 9O3K93S3TK)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
Aluminum Oxide (UNII: LMI26O6933)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Methylisothiazolinone (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66163-6503-2	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	01/01/2019	

Labeler - Cosmetic Solutions LLC (807907928)

Revised: 9/2019

Cosmetic Solutions LLC