

SYS- octinoxate, titanium dioxide lotion
AdvoCare International L.P.

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.

SYS

Drug Facts

Active Ingredients

Octinoxate 7.5%

Titanium Dioxide 6.0%

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (see Direction), 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. If contact occurs rinse with water to remove.

Stop use and ask a doctor if rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions

- Apply liberally 15 minutes before sun exposure.
- Reapply at least every 2 hours
- Use water resistant sunscreen if 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 skin 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, cyclopentasiloxane, glycerin, cetyl ethylhexanoate, tribehenin PEG-20 esters, caprylyl methicone, dimethicone, stearic acid, polyglyceryl-3 polydimethylsiloxyethyl dimethicone, polysorbate 80, aluminum hydroxide, squalane, isohexadecane, sodium acrylate/sodium acryloyldimethyl taurate/acrylamide copolymer, hydroxyacetophenone, dimethicone/PEG-10/15 crosspolymer, cetyl alcohol, nylon-12, linoleic acid, palmitoyl tripeptide-5, 1,2-hexanediol, caprylyl glycol, dextrin, hydrolyzed hibiscus esculentus extract, sodium hyaluronate, xanthan gum, tocopherol, disodium EDTA, sodium hydroxide, vitis vinifera (grape) seed extract, glycine soja (Soybean) oil, fragrance, algae extract, glycine soja (soybean) seed extract, ergocalciferol, linolenic acid, camellia sinensis leaf extract, aloe barbadensis leaf extract, potassium sorbate, sodium benzoate, ascorbic acid

Other Information

- protect this product from excessive heat and direct sun

Questions or comments?

Call 800-542-4800

Made in USA. Manufactured for and distributed by AdvoCare International L.P. Plano, TX 75074
www.advocare.com

Principal Display

SYS

supplement your skin

day

moisturizer

with sunscreen

broad spectrum SPF 20

with vitamins C, D, E and F

and hibiscus and grape seed extracts

Drug Facts

Active ingredients.....

Purpose

Octinoxate 7.5% sunscreen
Titanium Dioxide 6.0% 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 this product** keep out of eyes. If contact occurs rinse with water to remove.
- **Stop use and ask a doctor** if rash occurs.
- **Keep out of reach of children.** If swallowed, get medical help or contact a poison control center right away.

Directions

- Apply liberally 15 minutes before sun exposure.
- Reapply at least every 2 hours
- Use water resistant sunscreen if 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 skin 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

Continue ▶

Drug Facts (continued)

Inactive ingredients

Water, Cyclopentasiloxane, Glycerin, Cetyl Ethylhexanoate, Tribehnenin PEG-20 Esters, Caprylyl Methicone, Dimethicone, Stearic Acid, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Polysorbate 80, Aluminum Hydroxide, Squalane, Isohexadecane, Sodium Acrylate/Sodium Acryloyldimethyl Taurate/Acrylamide Copolymer, Hydroxyacetophenone, Dimethicone/PEG-10/15 Crosspolymer, Cetyl Alcohol, Nylon-12, Linoleic Acid, Palmitoyl Tripeptide-5, 1,2-Hexanediol, Caprylyl Glycol, Dextrin, Hydrolyzed Hibiscus Esculentus Extract, Sodium Hyaluronate, Xanthan Gum, Tocopherol, Disodium EDTA, Sodium Hydroxide, Vitis Vinifera (Grape) Seed Extract, Glycine Soja (Soybean) Oil, Fragrance, Algae Extract, Glycine Soja (Soybean) Seed Extract, Ergocaliferol, Linderic Acid, Camellia Sinensis Leaf Extract, Aloe Barbadosensis Leaf Extract, Potassium Sorbate, Sodium Benzoate, Ascorbic Acid

Other Information

- protect this product from excessive heat and direct sun

Questions or comments?

Call 800-542-4800
Made in USA. Manufactured for and distributed by AdvoCare International L.P. Plano, TX 75074 www.advocare.com



day
moisturizer
with sunscreen

broad spectrum SPF 20 with vitamins C, D, E and F, and hibiscus and grape seed extracts

1.7 FL OZ / 50 mL

Rich with vitamins and antioxidants, SYS™ Day with broad spectrum sunscreen hydrates, nourishes, and protects your skin to help combat the effects of aging and promote smoother, healthier looking skin.

NO INK BACK SIDE

SYS

octinoxate, titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68990-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.75 g in 50 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	3 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL ETHYLHEXANOATE (UNII: 134647WMX4)	
TRIBEHENIN PEG-20 ESTERS (UNII: 84K9EH29Y9)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
SQUALANE (UNII: GW89575KF9)	
ISOHEXADECANE (UNII: 918X10UF1E)	
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (400000 MW) (UNII: 1DXE3F3OZX)	
4-HYDROXY ACETOPHENONE (UNII: G1L3HT4CMH)	
NYLON-12 (UNII: 446U8J075B)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
PALMITOYL TRIPEPTIDE-5 (UNII: 2A3916MQHO)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ICODextrin (UNII: 2NX48Z0A9G)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TOCOPHEROL (UNII: R0ZB2556P8)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
VITIS VINIFERA SEED (UNII: C34U15ICXA)	
SOYBEAN OIL (UNII: 241ATL177A)	
SOYBEAN (UNII: L7HT8F1ZOD)	
ERGOCALCIFEROL (UNII: VS041H42XC)	
LINOLENIC ACID (UNII: 0RBV727H71)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68990-001-01	50 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/01/2014	

Labeler - AdvoCare International L.P. (799232707)

Revised: 6/2014

AdvoCare International L.P.