

VANICREAM SUNSCREEN BROAD SPECTRUM SPF 35- octinoxate and zinc oxide cream
Pharmaceutical Specialties, 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.

VANICREAM Sunscreen Sport BROAD SPECTRUM SPF 35

Drug Facts

Active ingredients

Octinoxate 2.8%

Zinc Oxide 11%

Purpose

Sunscreen

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. 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:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
 - 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

Other information protect this product from excessive heat and direct sun

Inactive ingredients C20-40 alcohols, cetyl PEG/PPG-10/1 dimethicone, cyclohexasiloxane, cyclopentasiloxane, cyclotetrasiloxane, dimethiconol, glycerin, hydrogenated castor oil, magnesium chloride, PEG-30 dipolyhydroxystearate, polypropyl silsesquioxane, purified water, tridecyl neopentanoate, triethoxycaprylylsilane, trimethylsiloxy silicate, ubiquinone (coenzyme Q10)

Questions or Comments? 800-325-8232

www.vanicream.com Official Vanicream
PHARMACEUTICAL SPECIALTIES, INC.
ROCHESTER, MN 55901 Made in USA

Vanicream™ Sunscreen Sport SPF 35 for sensitive skin is free of dyes, fragrance, masking fragrance, lanolin, parabens, formaldehyde & other preservatives.

- Oil-free
- Non-comedogenic (safe for use on face)
- Odorless
- Non-greasy
- No oxybenzone
- PABA-free
- Gluten-free
- Water resistant (80 minutes)

Formulated with zinc oxide and octinoxate, Vanicream™ Sunscreen Sport SPF 35 is lightweight, easy-to-spread, quickly absorbed, and transparent.

Recommended for daily use by the entire family. Ideal for even the most delicate, sensitive skin. (*see Directions*)

Dermatologist Recommended

When Vanicream™ Sunscreen Sport SPF 35 is used as directed with other sun protective measures, it helps provide protection from the sun's harmful rays (UVA and UVB) and decreases the risk of skin cancer and skin aging.

Coenzyme Q10 is an antioxidant which helps prevent damage to the skin by neutralizing free radicals produced when skin is exposed to the sun.

For information on our other products for sensitive skin, visit our website at www.vanicream.com or call **1-800-325-8232**.

Official Vanicream

for Sensitive Skin

Kid Friendly

NDC 45334-355-04

DERMATOLOGIST RECOMMENDED

VANICREAM™

Sunscreen Sport

BROAD SPECTRUM

SPF 35




FOR SENSITIVE SKIN

WATER RESISTANT (80 MINUTES)

NON-COMEDOGENIC

Free of dyes, fragrance, masking fragrance, lanolin, parabens, formaldehyde, & other preservatives

Net Wt. 4 oz (113 g)

<p>Drug Facts</p> <p>Active Ingredients Purpose Octinoxate 2.8%..... Sunscreen Zinc oxide 11%..... Sunscreen</p> <p>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</p> <p>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 swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions • apply liberally 15 minutes before sun exposure • reapply: • after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours • 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</p> <p>Other information protect this product from excessive heat and direct sun</p> <p>Inactive ingredients C20-40 alcohols, cetyl PEG/PPG-10/1 dimethicone, cyclohexasiloxane, cyclopentasiloxane, cyclotetrasiloxane, dimethiconol, glycerin, hydrogenated castor oil, magnesium chloride, PEG-30 dipolyhydroxyolefinate, polypropyl silsesquioxane, purified water, hloteryl neopentanoate, triethoxycaprylylsilane, trimethylsilyl silicate, ubiquinone (coenzyme Q10)</p> <p>Questions or Comments? 800-325-8232 www.vanicream.com Official Vanicream</p>	<p>Vanicream® Sunscreen Sport SPF 35 for sensitive skin is free of dyes, fragrance, masking fragrance, lanolin, parabens, formaldehyde & other preservatives.</p> <ul style="list-style-type: none"> • Oil-free • Non-comedogenic (safe for use on face) • Odorless • Non-greasy • No oxybenzone • PABA-free • Gluten-free • Water resistant (80 minutes) <p>Formulated with zinc oxide and octinoxate, Vanicream® Sunscreen Sport SPF 35 is lightweight, easy-to-spread, quickly absorbed, and transparent.</p> <p>Recommended for daily use by the entire family. Ideal for even the most delicate, sensitive skin. (see Directions)</p> <p>Vanicream is a trademark, registered trademark of Pharmaceutical Specialties, Inc. in the US and other countries. ©PS 2012. All rights reserved.</p>	<p>NDC 45334-355-04 DERMATOLOGIST RECOMMENDED</p> <p>VANICREAM™ Sunscreen Sport</p> <p>BROAD SPECTRUM SPF 35</p>  <p>FOR SENSITIVE SKIN WATER RESISTANT (80 MINUTES) NON-COMEDOGENIC</p> <p>Free of dyes, fragrance, masking fragrance, lanolin, parabens, formaldehyde, & other preservatives</p> <p>Net Wt 4 oz (113 g)</p>	<p>Dermatologist Recommended</p> <p>When Vanicream® Sunscreen Sport SPF 35 is used as directed with other sun protective measures, it helps provide protection from the sun's harmful rays (UVA and UVB) and decreases the risk of skin cancer and skin aging.</p> <p>Coenzyme Q10 is an antioxidant which helps prevent damage to the skin by neutralizing free radicals produced when skin is exposed to the sun.</p> <p>For information on our other products for sensitive skin, visit our website at www.vanicream.com or call 1-800-325-8232.</p> <p>Official Vanicream</p> <p>for Sensitive Skin</p>  
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VANICREAM SUNSCREEN BROAD SPECTRUM SPF 35

octinoxate and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45334-355
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.028 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.11 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
C20-40 ALCOHOLS (MP 79C) (UNII: SBX8KS13SG)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
CYCLOMETHICONE 4 (UNII: CZ227117JE)	
DIMETHICONOL GUM (UNII: 4MJ9GU3T1P)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	

MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
PROPYLSILSESQUIOXANE, HYDROGEN TERMINATED (UNII: 2PDG9JR76G)	
WATER (UNII: 059QF0KO0R)	
TRIDECYL NEOPENTANOATE (UNII: 3Z8H1DA7J5)	
UBIDECARENONE (UNII: EJ27X76M46)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SILICA, TRIMETHYLSILYL CAPPED (UNII: VU10KU4B9S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45334-355-04	1 in 1 CARTON	04/18/2013	
1		113 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:45334-355-02	57 g in 1 TUBE; Type 0: Not a Combination Product	04/18/2013	
3	NDC:45334-355-07	7 g in 1 TUBE; Type 0: Not a Combination Product	04/18/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/18/2013	

Labeler - Pharmaceutical Specialties, Inc. (076499557)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmaceutical Specialties, Inc.		076499557	manufacture(45334-355) , pack(45334-355)

Revised: 10/2017

Pharmaceutical Specialties, Inc.