VANICREAM- titanium dioxide 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 BROAD SPECTRUM SPF 30

Drug Facts

Active Ingredients:	Purpose
Titanium Dioxide 3%	Sunscreen
Zinc Oxide 11%	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

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Do not use On damaged or broken skin

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:
 - o after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- children under 6 months: 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 Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - o limit time in the sun, especially from 10 a.m. -2 p.m.
 - wear long-sleeved shirts, pants, hats and sunglasses

Inactive Ingredients

C20-40 alcohols, cetyl PEG/PPG-1 0/1 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

PRINCIPAL DISPLAY PANEL - 113 g Tube Carton



VANICREAM™ Sunscreen Sport BROAD SPECTRUM SPF 35
FOR SENSITIVE SKIN
WATER RESISTANT (80 MINUTES)
NON-COMEDOGENIC
Free of dyes, lanolin, fragrance,
masking fragrance,
parabens, formaldehyde,
& other preservatives

Net Wt 4 oz (113 g)

PRINCIPAL DISPLAY PANEL - 7 g Tube Label



Sunscreen Sport For Sensitive Skin Free of dyes, Ianolin, fragrance, masking fragrance, parabens, formaldehyde & other preservatives

Active ingredients: Octinoxate 3%, Zinc oxide 11% (Sunscreens) 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) Uses: helps prevent sunburn Warnings: For external use only. Keep out of eyes, rinse with water to remove. Stop use and ask a doctor if rash occurs. Do not use on damaged or broken skin. Keep out of reach of children. Directions: apply liberally 15 minutes before sun exposure, reapply after 80 min of swimming or sweating, after towel drying, at least every 2 hrs. Children under 6 months: Ask a doctor.

Professional Sample. Not for sale. AT12W S3503

VANICREAM™ BROAD SPECTRUM SPF 35 WATER RESISTANT (80 MINUTES) - NON-COMEDOGENIC

PHARMACEUTICAL SPECIALITIES, INC. Made In USA

www.vaniceram.com 800-325-8232

SUNSCREEN SPORT

For Sensitive Skin

Free of dyes, lanolin, fragrance, masking fragrance,

parabens, formaldehyde,

&

other preservatives

VANICREAM

titanium dioxide and zinc oxide cream

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

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Titanium Dioxide (Titanium Dioxide)	Titanium Dio xide	0.03 g in 1 g		
Zinc Oxide (Zinc Oxide)	Zinc Oxide	0.11 g in 1 g		

Inactive Ingredients				
Ingredient Name	Strength			
CYCLOMETHICONE 6				
CYCLOMETHICONE 5				
CYCLOMETHICONE 4				
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5)				
DIMETHICONOL (40 CST)				
GLYCERIN				
HYDRO GENATED CASTOR OIL				
MAGNESIUM CHLO RIDE				
PEG-30 DIPOLYHYDROXYSTEARATE				
WATER				
TRIDECYL NEO PENTANO ATE				
TRIETHO XYCAPRYLYLSILANE				
TRIMETHYLSILO XYSILICATE (M/Q 0.6-0.8)				
UBIDECARENO NE				

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:45334-355-04	1 in 1 CARTON		

1	113 g in 1 TUBE			
2 NDC:45334-355-07	7 g in 1 TUBE			
Marketing Information				
Marketing Category	Application Number or Monogra	aph Citation	Marketing Start D	ate Marketing End Date
OTC monograph final	part352		0 2/0 1/20 12	

Labeler - Pharmaceutical Specialties, Inc. (076499557)

Registrant - Pharmaceutical Specialties, Inc. (076499557)

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

Revised: 4/2014 Pharmaceutical Specialties, Inc.