

**PHYSICAL FACIAL BLOCK SPF 30- zinc oxide, titanium dioxide cream**  
**Vivier Pharma, 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.*

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**Physical Facial Block**

**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 or irritation develops and lasts.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

**Active Ingredients**

10% Titanium Dioxide

8% Zinc Oxide

**Purpose**

Sunscreen

Sunscreen

**Uses**

Helps prevent sunburn. ■ Provides broadspectrum UVA/UVB protection. ■ Ideal for daily use; can be applied under makeup. ■ Optimal for post-care or on sensitive skin.

**Directions**

Apply daily to face, neck and chest. ■ Apply liberally 15-30 minutes before sun exposure and as needed. ■ Reapply after towel drying, swimming or sweating. ■ For children under six months of age, consult a physician.

**Inactive Ingredients**

Alumina, Ammonium Acryloyldimethyltaurate, Bis-PEG/PPG-16/16 PEG/PPG16/16 Dimethicone, Butylparaben, Camellia Sinensis (Green Tea) Extract, Caprylic/Capric Triglyceride, Ceteareth 20, Cetearyl Alcohol, Cetyl Dimethicone, Citrus Medica Limonum (Lemon Bioflavonoids) Peel Extract, Cyclomethicone, C12-15 Alkyl Benzoate, Dimethicone, Dipropylene Glycol Dibenzoate, Eicosene Copolymer, Ethylparaben, Glycerin, Glyceryl Stearate, Isopropyl Titanium Triisostearate

/Triethoxycaprylyl Crosspolymer, Methylparaben, Phenoxyethanol, Polyhydroxystearic Acid, Polysorbate 20, PPG-15 Stearyl Ether Benzoate, Propylparaben, Pyrus Malus (Apple) Fruit Extract, Saccharum Officinarum (Sugar Cane) Extract, Sodium Ascorbyl Phosphate, Tocopheryl Acetate, Water/Eau, Xanthan Gum.

## Principal Display Panel

Physical Facial Block SPF 30 US Carton 07-6046-04

DRUG FACTS	
<b>ACTIVE INGREDIENTS</b>	<b>PURPOSE</b>
10% Titanium Dioxide	Sunscreen
8% Zinc Oxide	Sunscreen
<b>USES</b>	
<ul style="list-style-type: none"> <li>Helps prevent sunburn.</li> <li>Provides broad-spectrum UVA/UVB protection.</li> <li>Ideal for daily use; can be applied under makeup.</li> <li>Optimal for post-care or on sensitive skin.</li> </ul>	
<b>WARNINGS</b> For external use only	
<b>When using this product</b>	
<ul style="list-style-type: none"> <li>Keep out of eyes. Rinse with water to remove.</li> </ul>	
<b>Stop use and ask a doctor if</b>	
<ul style="list-style-type: none"> <li>Rash or irritation develops and lasts.</li> </ul>	
<b>Keep out of reach of children.</b>	
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<b>DIRECTIONS</b>	
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<b>Questions or Comments</b>	
450 455 9779	1 877 484 8437

Store at room temperature (15-30°C / 59-86°F).

Mfd. for Vivier Pharma  
Champlain NY USA 12919  
Made in Canada  
07-6046-04  
vivierpharma.com

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Oil-free  
Alcohol-free  
Fragrance-free  
Recommended by physicians



NDC 67226-2330-6

Oil-free  
Alcohol-free  
Fragrance-free  
Recommended by physicians

Skin Tx  
SKIN TREATMENT SYSTEM



Physical Facial Block  
SPF 30

2 fl oz  
60 mL

## PHYSICAL FACIAL BLOCK SPF 30

zinc oxide, titanium dioxide cream

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:67226-2330

Route of Administration TOPICAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	4.8 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	6 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LM26O6933)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE (UNII: KBC00G95HI)	
BUTYLPARABEN (UNII: 3QP1U3FV8)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIPROPYLENE GLYCOL DIBENZOATE (UNII: 6OA5ZDY41O)	
ETHYLPARABEN (UNII: 14255EXE39)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL TITANIUM TRIISOSTEARATE (UNII: 949E3KBJ1I)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PPG-15 STEARYL ETHER BENZOATE (UNII: 80D2J6361M)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0K00R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SUGARCANE (UNII: 81H2R5AOH3)	
APPLE (UNII: B423VGH5S9)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
BIS-PEG/PPG-16/16 PEG/PPG-16/16 DIMETHICONE (UNII: 55A74AJ3KB)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
CITRUS BIOFLAVONOIDS (UNII: BD70459I50)	
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67226-2330-6	1 in 1 BOX		
1		60 mL in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/28/2006	

**Labeler** - Vivier Pharma, Inc. (250996550)

## Establishment

Name	Address	ID/FEI	Business Operations
Vivier Pharma, Inc.		250996550	manufacture(67226-2330)

Revised: 4/2014

Vivier Pharma, Inc.