

CREAM- zinc oxide, titanium dioxide lotion
Oxygen Development 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.

Tarte high - performance naturals BB tinted treatment primer Broad Spectrum SPF 30 Sunscreen

Active Ingredients

Titanium Dioxide 4.55%

Zinc Oxide 3.5%

Purpose

Sunscreen

Uses

Helps prevent sunburn. If used as directed with other sun protection measures (see directions), decreases the risk of skin cancer and early aging caused by the sun.

Warnings

For external use only. Stop use and ask a doctor if rash occurs. Do not use on damage or broken skin.

When using this product

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

Keep out of the reach of children.

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

Directions

Shake before use. Apply liberally 15 minutes before sun exposure. Use a water resistant sunscreen if swimming or sweating. Reapply 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 the 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

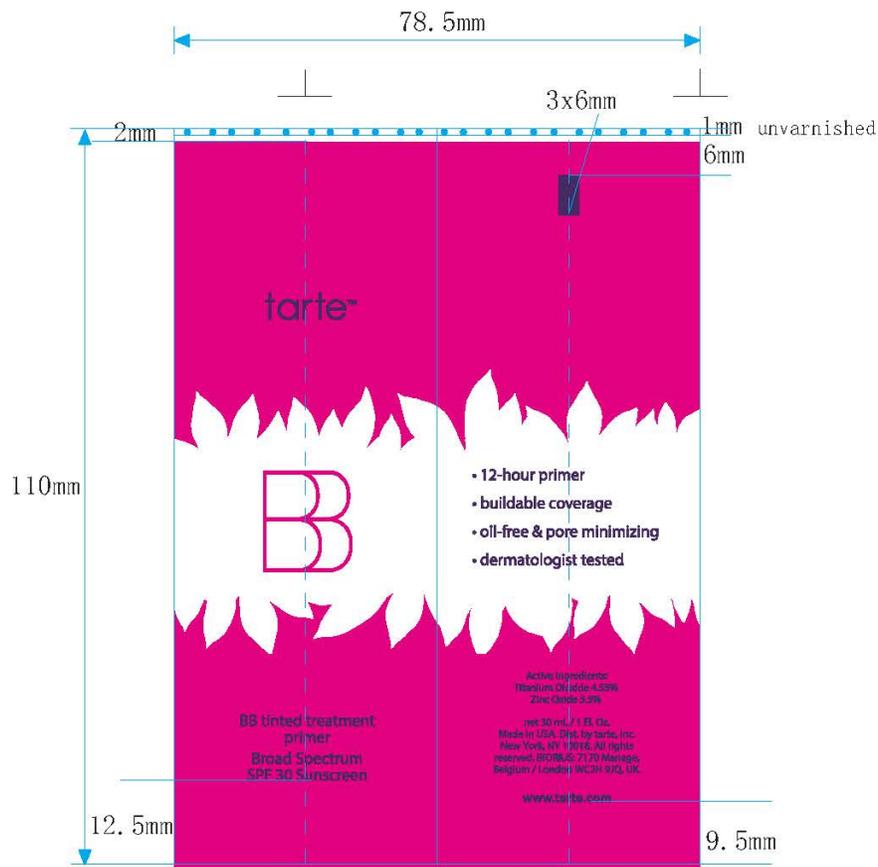
Protect the product in this container from excessive heat and direct sunlight.

You may report a serious adverse reaction to: tarte c/o Report Reaction, LLC, P.O. Box 22, Plainsboro, NJ 08536-0222

Inactive Ingredients

Cyclopentasiloxane, Isododecane, Polysilicone-11, Polymethylsilsesquioxane, Hexyl Laurate, PEG-10 Dimethicone, Polyglyceryl-4 Isostearate, Stearic Acid, Cetyl PEG/PPG-10/1 Dimethicone, Alumina, Triethoxycaprylylsilane, Dipalmitoyl Hydroxyproline, Diamond Powder

Package label



320471 (2) | 丝网印 (Silkscreen) : white 269c

- white
- 269c
- die line, does not print
(边框, 不印刷)
- unvarnished area

产品编号 P/N	320471 (2)	制作人 Processed by	Mary	确认签字 Approval	
打样/订单号 Sample/PO #		制作日期 Date	2020/07/27	日期 Date	
附加说明 Remarks					

Package

- K
- M
- P8780C
- P8080C
- dieline

light
12-hour primer

tarte
high-performance naturals™

• triple-B complex:
blend of natural
diamond powder,
plants & lipoamino
acid

• pore minimizing,
smoothing &
brightening

• 12-hour primer &
dermatologist
tested

• wear alone for a
sheer tint or under
foundation for
enhanced coverage

**Drug Facts
(continued)**

**Inactive
Ingredients**

Cyclopentasiloxane,
isododecane,
polysilicone-11, mica,
polymethylsilsesqui-
oxane, hexyl laurate,
PEG-10 dimethicone,
polyglyceryl-4
isostearate, stearic
acid, cetyl
PEG/PPG-10M
dimethicone,
alumina,
trithoxycaprylylsil-
lane, dipalmitoyl
hydroxyproline,
diamond powder, Iron

Drug Facts

Active Ingredients	Purpose
Titanium Dioxide 4.55%.....	Sunscreen
Zinc Oxide 3.5%.....	Sunscreen

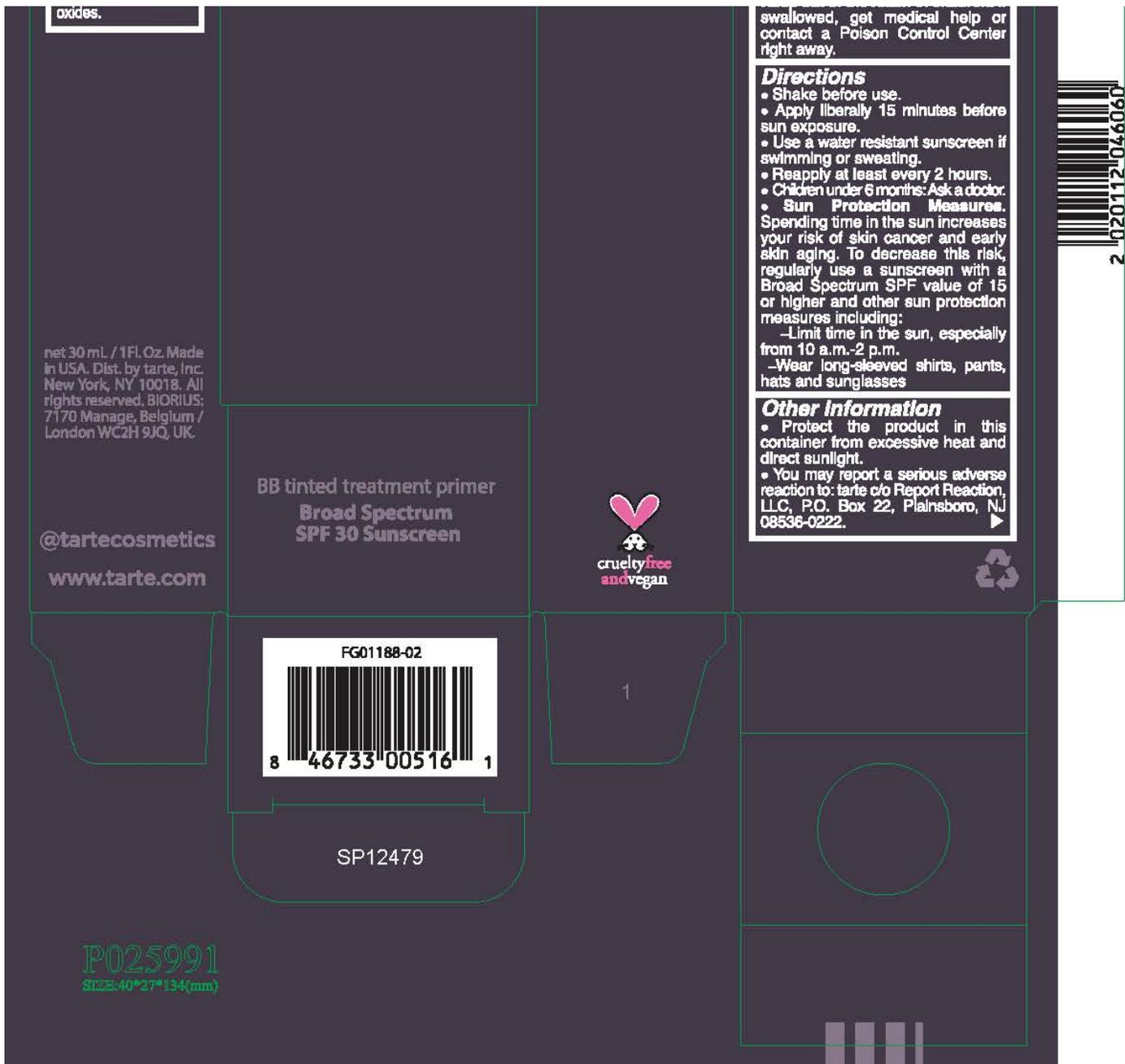
Uses

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- 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.

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CTT014606



CREAM

zinc oxide, titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61354-053
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	3.49 mg in 100 mg
TITANIUM DIOXIDE (UNII: 15FIX9V2IP) (TITANIUM DIOXIDE -	TITANIUM DIOXIDE	4.54 mg

UNII:15FIX9V2JP)

TITANIUM DIOXIDE

in 100 mg

Inactive Ingredients

Ingredient Name	Strength
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	3.19 mg in 100 mg
HEXYL LAURATE (UNII: 4CG9F9W01Q)	1.76 mg in 100 mg
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	1.65 mg in 100 mg
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	1.5 mg in 100 mg
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	55.74 mg in 100 mg
ISODODECANE (UNII: A8289P68Y2)	10.69 mg in 100 mg
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	4.68 mg in 100 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-053-01	1 in 1 CARTON	05/03/2022	
1		1 mg in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/03/2022	

Labeler - Oxygen Development LLC (137098492)**Establishment**

Name	Address	ID/FEI	Business Operations
Oxygen Development LLC		137098492	manufacture(61354-053)

Revised: 5/2022

Oxygen Development LLC