UNISEX BB TINT- IT S CLEAR - 6553- titanium dioxide cream Faberlic Joint Stock Company

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.

Unisex BB Tint- It's Clear - 6553

Drug Facts

Active ingredients

Titanium Dioxide, 7.47%

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 skin aging caused by the sun

Warnings

For external use only

Do not use

on damage 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 product is swallowed get medical help or contact a Poison Control Center right away

Directions

- Apply liberally 15 minutes before sun exposure
- Children undre 6 months of age: Ask a doctor
- Reapply at least every 2 hours

- Use a water resistant sunscreen if swimming or sweating
- Sun protection measures.
- Spending time in the sun increases your risk of skin cancer and early skin aging. To
 decrease this risk, reguarly 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.

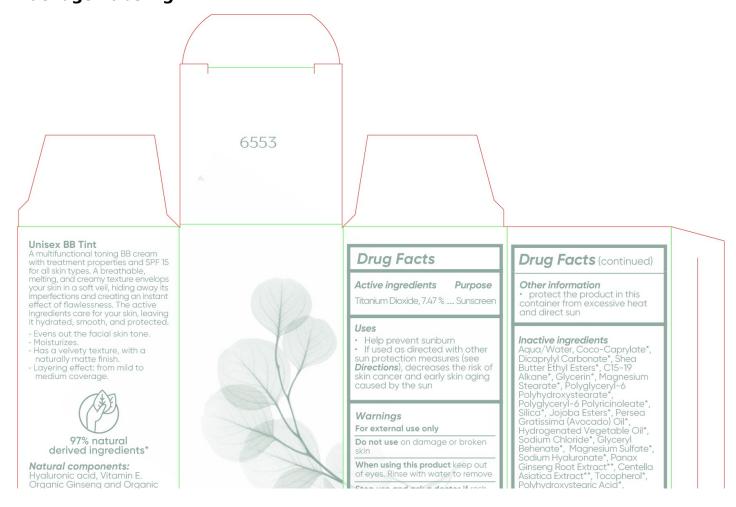
Other information

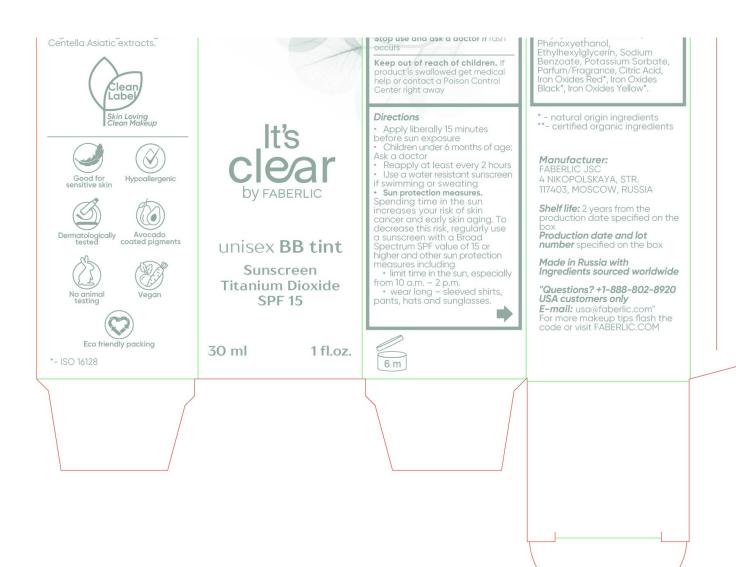
protect the product in this container from excessive heat and direct sun

Inactive ingredients

Aqua/Water, Coco-Caprylate*, Dicaprylyl Carbonate*, Shea Butter Ethyl Ester*, C15-19 Alkane*, Glycerin*, Magnesium Stearate*, Polyglyceryl-6 Polyhydroxystearate*, Polyglyceryl-6 Polyricinoleate*, Silica*, Jojoba Esters*, Persea Gratissima (Avocado) Oil*, Hydrogenated Vegetable Oil*, Sodium Chloride*, Glyceryl Behenate*, Magnesium Sulfate*, Sodium Hyaluronate*, Panax Ginseng Root Extract**, CentellaAsiatica Extract**, Tocopherol*, Polyhydroxystearic Acid*, Phenoxyethanol, Ethylhexylglycerin, Sodium Benzoate, Potassium Sorbate, Parfum/Fragrance, Citric Acid, Iron Oxides Red*, Iron Oxides Yellow*.

Package Labeling:





UNISEX BB TINT- IT S CLEAR - 6553

titanium dioxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82063-6553
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	74.7 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
COCO-CAPRYLATE (UNII: 4828G836N6)		
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)		

SHEA BUTTER ETHYL ESTERS (UNII: V2CI786FPG)	
C15-19 ALKANE (UNII: CI87N1IM01)	
GLYCERIN (UNII: PDC6A3C0OX)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYGLYCERYL-6 POLYRICINOLEATE (UNII: YPM0ZOC2HR)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
CENTELLA ASIATICA TRITERPENOIDS (UNII: 4YS74Q4G4J)	
TOCOPHEROL (UNII: ROZB2556P8)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:82063- 6553-0	1 in 1 CARTON	01/11/2022		
1		30 mL 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 not final	part352	01/11/2022	
	part352	01/11/2022	

Labeler - Faberlic Joint Stock Company (365955546)

Revised: 12/2021 Faberlic Joint Stock Company