BELLI PURE RADIANCE FACIAL SUNSCREEN TINTED PROTECTION SPF 25titanium dioxide, zinc oxide cream BODY HALO 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.

BODY HALO - Belli - Pure Radiance Facial Sunscreen Tinted Protection SPF 25 (42281-003)

Active ingredient

Titanium Dioxide (7%) Zinc Oxide (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 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 or skin irritation develops and lasts

Keep out of reach of children.

In case of accidental ingestion, contact a Poison Control Center immediately.

Directions

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

- 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

Other information

Store below 25 degree C/77 degree F.

Inactive ingredients

Butylene Glycol, C12-15 Alkyl Benzoate, Cetearyl Alcohol, Cetyl Alcohol, Cyclomethicone, Deionized Water, Glycereth-2 Cocoate, Glycerine, Glyceryl Stearate, Hydrolyzed Collagen (Marine Derived) Iodopropynyl Butylcarbamate, Iron Oxides, Isopropyl Palmitate, Octyldodecyl Neopentanoate, PEG-100 Stearate, Phenoxyethanol, Polyglyceryl-2 Diisostearate, Sodium PCA, Tocopheryl Acetate (Vitamin E), Xanthan Gum

Belli	Befti [®] is Picky for a Purpose™ to give you peace of mind. Our products are allergy tested, free of artificial dyes or fragrances, phthalates and paraben preservatives.
PURE RADIANCE FACIAL SUNSCREEN	Shield yourself from UVA and UVB rays with trusted mineral sunscreen ingredients. Oil-free.
Tinted Protection PROTECT	 limit time in the sun, especially from 10 a.m 2 p.m. wear long-sleeved shirts, pants, hats and sunglasses apply liberally 15 minutes before sun
SPF 25 ZINC OXIDE	 exposure use a water resistant sunscreen if swimming or sweating reapply at least every 2 hours children under 6 months: ask a doctor
• TITANIUM DIOXIDE <i>Picky for a Purpose</i> * OB/GYN & DERMATOLOGIST RECOMMENDED 1.5 FL. OZ./ 44 ML @	WARNINGS: See outer carton. NDC Number: (42281-003-01) WWW. BELLISKINCARE. COM MANUFACTURED IN THE USA FOR ABT-BELLI MATERNA, INC., SUWANEE, GA 30024

Belli

is *Picky for a Purpose*" to give you peace of mind. Our roducts are allergy tested, free of artificial dyes or fragrances, phthalates and paraben

Drug Facts Active ingredient Purpose Ttanium Dioxide (7%) Sunscreen Zinc Oxide (5%) Sunscreen Uses In the sum protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun Warnings	Sun exposure can result in unsightly discoloration and uneven skin tone. Shield yourself from UVA and UVB rays with trusted mineral sunscreen ingredients. Lightweight oil-free formula for all skin types, may be worn alone or underneath makeup.	PURE RADIANCE FACIAL SUNSCREEN Tinted Protection	Belli [®] is Picky for a Purpose ^w Belli [®] delivers trusted skin care solutions that pamper and protect without known
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 skin irritation develops and lasts	Lightly tinted. SPF 25. Use with Bellt* Healthy Glow Facial Hydrator for best results.	PROTECT	harmful chemicals. The ingredients in Belli® products are selected based upon an extensive review of published medical studies.
Keep out of reach of children. In case of accidental ingestion, contact a Poison Control Center immediately. Directions 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 sursceen 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 sunglesses ■ 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	NDC Number: (42281-003-01) Drug Facts (continued) Other information Store below 25°C/77F: Inactive ingredients Butylene Glycol, C12-15 Alkyl Benzoate, Ceteareth-20, Cetearyl Alcohol, Cetyl Alcohol, Cyclamethicone, Deionized Water, Glycereth-2 Cocoate, Glycerine, Glyceryl Stearete, Hydrolyzed Collagen Marine Derived), lodopropynyl Butylcartamate, Iron Obides, isopropyl Palmitate, Octyldodecyl Neopentanoste, PEG-100 Stearete, Phenoxyethanol, Polyglyceryl-2 Disostearate, Sodium PCA, Tocopheryl Acetate (Vitamin E), Xenthan Gum	• SPF 25 • ZINC OXIDE • TITANIUM DIOXIDE Picky for a Purpose* OBVGYN & DERMATOLOGIST RECOMMENDED 1.5 FL. 02/44 ML O	Every Belli [®] product is allergy tested, free of artificial dyes or fragrances, phthalates and paraben preservatives. Belli [®] even follows a unique safety screening process to avoid ingredients with known links to birth defects or harmful effects while breastfeeding. Expect Beautiful Skin. Enjoy Peace of Mind."
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BELLI PURE RADIANCE FACIAL SUNSCREEN TINTED PROTECTION SPF 25

titanium dioxide, zinc oxide cream

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (S	ource)	NDC:42	2281-003
Route of Administration	TOPICAL				
Active Ingredient/Active	Moiety				
Ingre	dient Name		Basis of Stre	ngth	Strength

TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	70 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) Z	ZINC OXIDE	50 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
WATER (UNII: 059QF0KO0R)	
GLYCERETH-2 COCOATE (UNII: JWM00VS7HC)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
MARINE COLLAGEN, SOLUBLE (UNII: 8JC99XGU4W)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-2 DIISOSTEARATE (UNII: DG195GP57P)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 4690TG57A2)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:42281- 003-01	1 in 1 CARTON	02/01/2022	
1		44 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
м	arketing	Information		
Μ	arketing	Information		
M	arketing Marketing Category	Information Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

Labeler - BODY HALO LLC (080337757)