

GOLD COLLAGEN AMPOULE COVER CAKE SPF50 N203- octinoxate, octisalate, titanium dioxide and zinc oxide cream powder
THEFACESHOP CO., LTD.

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.

TFS GOLD COLLAGEN AMPOULE COVER CAKE SPF50 PA+++N203 34200260

Active Ingredients

Octinoxate 6.0 %
Octisalate 2.0 %
Titanium Dioxide 15.4 %
Zinc Oxide 4.9 %

Purpose

Sunscreen
Sunscreen
Sunscreen
Sunscreen

Uses

Helps prevent sunburn

Warnings

For external use only.

Do not use on damaged 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 generously and evenly 15 minutes before sun exposure.

Children under 6 months of age: Ask a doctor.

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.

Reapply at least every 2 hours.

Use a water-resistant sunscreen if swimming or sweating.

Dispense an adequate amount onto the puff and apply to skin. Pat skin lightly to boost absorption.

Other Information

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51523-260
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	1.7 g in 11 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.5 g in 11 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.7 g in 11 g
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	0.2 g in 11 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51523-260-11	1 in 1 CARTON	12/31/2015	
1		11 g in 1 CONTAINER; 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	12/31/2015	

Labeler - THEFACESHOP CO., LTD. (688329416)

Registrant - THEFACESHOP NORTH AMERICA, INC. (620459193)

Establishment

Name	Address	ID/FEI	Business Operations
THEFACESHOP CO., LTD.		688329416	label(51523-260)

Revised: 8/2015

THEFACESHOP CO., LTD.