IMPACT FIX PRISM TWO WAY CAKE BROAD SPECTRUM SPF 24- octinoxate, titanium dioxide, zinc oxide powder Dong Sung Bio Pharm. 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.

42361-123 Drug Facts

Drug Facts

Octinoxate 1.4%
Titanium Dioxide 6.8%
Zinc Oxide 3.9%

Drug Facts

Sunscreen

Uses

Not only will it help prevent sunburn, it also reduces the risk of skin cancer and early skin aging if used as directed with other sun protection measures. (SPF value of 15 or higher)

Warnings

For external use only. Do not use on damaged or broken skin. Discontinue use if signs of irritation or rash appear. Avoid contact with eyes. Wash off immediately with cold water if product comes in contact with eyes. Keep this and all drugs out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center right away.

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. and wear long-sleeved shirts, pants, hats and sunglasses. For use on skin only.

Keep this and all drugs out of reach of children. In case of accidental ingestion, seek professional assistance of contact a Poison Control Center right away.

Directions

At the end of basic skincare regimen, apply liberally on face to cover the entire facial area and lightly go over parts where extra cover-up is needed with detailed perfection. Apply 15 minutes before sun exposure. For added protection, reapply after 40 minutes of swimming or sweating, immediately after towel drying and/or at least every 2 hours.

Children under 6 months: Ask a doctor.

Inactive Ingredients

Talc, Mica, Silica, Hexyl Laurate, Dimethicone, Iron Oxide (CI 77492), Diisostearyl Malate, Mineral Oil, Phenyl Trimethicone, Squalane, Lauryl Methacrylate/Glycol Dimethacrylate Crosspolymer, Methicone, Dimethicone/Vinyl Dimethicone Crosspolymer, Iron Oxide (CI 77491), Dimethiconol

Stearate, Fragrance, Iron Oxides (CI 77499), Ultramarines (CI 77007), Methylparaben, Propylparaben, Simmondsia Chinensis (Jojoba) Seed Oil, Hydrolyzed Silk, Tocopheryl Acetate, Macadamia Integrifolia Seed Oil

Other Information

Protect this product from excessive heat and direct sun.

IMPACT

FIX PRISM TWO WAY CAKE

Broad Spectrum SPF 24

moisturizing two way cake

No. 23 True Beige



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Broad Spectrum SPF 24 moisturizing two way cake

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Other Information Protect this product from excessive heat and direct sun. Questions [comments]? (562) 802-0131 www.DS€shopusa.com

Distributed by Dong Sung World Wide USA, Inc. 13733 Milroy Pl., Santa Fe Springs, CA 90670

판매원 오마샤리프화장품 통 성제 약 주 십 의 사 서울특별시 서초구 방태분동 792~4 제조원 **포수에의장장품주식회사** 총청년도 마산시 음병인 소통리 33~21 소비자설당:080-020-2500





IMPACT FIX PRISM TWO WAY CAKE BROAD SPECTRUM SPF 24

octinoxate, titanium dioxide, zinc oxide powder

Product Information

HUMAN OTC DRUG Product Type Item Code (Source) NDC:42361-123

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	14 mg in 1 g
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	68 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	39 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
TALC (UNII: 7SEV7J4R1U)	
MICA (UNII: V8A1AW0880)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
DIISO STEARYL MALATE (UNII: QBS8 A3XZGQ)	

SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
MINERAL OIL (UNII: T5L8T28FGP)	
PHENYL TRIMETHICO NE (UNII: DR0 K5NOJ4R)	
SQUALANE (UNII: GW89575KF9)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)	
ULTRAMARINE BLUE (UNII: I39 WR998BI)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SIMMONDSIA CHINENSIS SEED (UNII: D24K2Q1F6H)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
MACADAMIA O IL (UNII: 515610 SU8C)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
LAURYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EX0F4CZ66H)	
DIMETHICO NE/VINYL DIMETHICO NE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

F	Packaging			
#	Item Code Package Description		Marketing Start Date	Marketing End Date
1	NDC:42361-123-01	1 in 1 CARTON	12/21/2017	
1		14 g in 1 CASE; Type 0: Not a Combination Product		
2	NDC:42361-123-02	14 g in 1 TRAY; Type 0: Not a Combination Product	12/21/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/21/2017	

Labeler - Dong Sung Bio Pharm. Co., Ltd. (687811661)

Registrant - Dong Sung World Wide USA, Inc. (784969219)

Establishment				
Name	Address	ID/FEI	Business Operations	
Dong Sung Bio Pharm. Co., Ltd.		687811661	label(42361-123)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Omar Sharif Cosmetic Co., Ltd.		689316318	manufacture(42361-123), pack(42361-123)	