RAF FIVE - KICK OFF HYDRATING BROAD SPECTRUM SPF30 SUNSCREEN- zinc oxide and titanium dioxide lotion Cosmetic Solutions 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.

RAF™ Five - Kick Off Hydrating Lotion BROAD SPECTRUM SPF30 SUNSCREEN Drug Facts

Active Ingredients

Titanium Dioxide 6.0% Zinc Oxide 7.5%

Purpose

Sunscreen

Uses

Helps prevent sunburn.

Warnings

For external use only

When using this product

Do not get into eyes. If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor.

If irritation or rash occurs.

Keep out of reach of children.

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

Directions

Apply liberally and spread evenly 15 minutes before sun exposure.

Reapply:

- After 80 minutes of swimming or sweating.
- Immediately after towel drying.
- At least every 2 hours.

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 broad spectrum SPF of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10 am 2 pm.
 - Wear long-sleeve shirts, pants, hats and sunglasses.
- Children under 6 months of age: Ask a doctor.

Other information

Protect this product from excessive heat and direct sun. Store at room temperature (59-85°).

Inactive ingredients

Water (Aqua), Caprylic/ Capric Triglyceride, Undecane, Pentylene Glycol, Steareth-2 Glycerin, Cetearyl Alcohol, Niacinamide, PPG-12/SMDI Copolymer, Silica, Steareth -21 Tridecane, Polyhydroxystearic Acid, Propanediol, Cannabidiol, Ergothioneine, Dipotassium Glycyrrhizate, Zingiber Officinale (Ginger) Root Extract, Artemisia Vulgaris Oil, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Citrus Limon (Lemon) Peel Oil, Eucalyptus Globulus Leaf Oil, Juniperus Virginiana Oil, Mentha Citrata Leaf Oil, Mentha Viridis (Spearmint) Leaf Oil, Vitis Vinifera (Grape) Seed Oil, Sodium Hyaluronate, Bisabolol, Alumina, Stearic Acid.

Distributed by ILERA DERM LLC, a subsidiary of Zelira Therapeutics LTD. 5110 Campus Drive Plymouth Meeting, PA 19462

PRINCIPAL DISPLAY PANEL - 50 mL Bottle Carton

RAF™ FIVE

KICK OFF HYDRATING LOTION

BROAD SPECTRUM SPF30 SUNSCREEN

with CBD

1.7 fl. oz. / 50 mL

Drug Facts (continued)

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sunscreen to protect skin from UV aging and UV sun burning rays while a hit of Hyaluronic acid hydrates skin.



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KICK OFF

BROAD SPECTRUM SPF30



RAF FIVE - KICK OFF HYDRATING BROAD SPECTRUM SPF30 SUNSCREEN

zinc oxide and titanium dioxide lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66163-4453	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	7.5 g in 100 mL	
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	6 g in 100 mL	

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	Strength
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Undecane (UNII: JV0QT00NUE)	
Pentylene Glycol (UNII: 50C1307PZG)	
Steareth-2 (UNII: V56DFE46J5)	
Glycerin (UNII: PDC6A3C0OX)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Niacinamide (UNII: 25X518RD4)	
PPG-12/SMDI Copolymer (UNII: 1BK9DDD24E)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Steareth-21 (UNII: 53J3F32P58)	
Tridecane (UNII: A3LZ F0L939)	
Propanediol (UNII: 5965N8W85T)	
Cannabidiol (UNII: 19GBJ60SN5)	
Ergothioneine (UNII: BDZ3DQM98W)	
Glycyrrhizinate Dipotassium (UNII: CA2Y0FE3FX)	
Ginger (UNII: C5529G5JPQ)	
Artemisia Vulgaris Top Oil (UNII: 72Q967Y48V)	
Bergamot Oil (UNII: 39W1PKE3JI)	
Lemon Oil, Cold Pressed (UNII: 19GRO824LL)	
Eucalyptus Oil (UNII: 2R04ONI662)	
Juniperus Virginiana Oil (UNII: PAD4FN7P2G)	
Spearmint Oil (UNII: C3M81465G5)	
Grape Seed Oil (UNII: 930MLC8XGG)	
Hyaluronate Sodium (UNII: YSE9PPT4TH)	
Levomenol (UNII: 24WE03BX2T)	
Aluminum Oxide (UNII: LMI26O6933)	

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:66163- 4453-1	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2021		

Marketing Information					
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
part352	03/01/2021				
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date			

Labeler - Cosmetic Solutions LLC (807907928)

Revised: 8/2021 Cosmetic Solutions LLC