KARI GRAN ESSENTIAL SPF SPF 28- zinc oxide lotion GRAN KARI INC

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.

KARI GRAN - ESSENTIAL SPF

ACTIVE INGREDIENT

NON-NANO ZINC OXIDE

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 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, SEEK MEDICAL ATTENTION OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

- SHAKE WELL. APPLY AT LEAST 1 PUMP TO FACE. APPLY ADDITIONAL PUMPS TO NECK AND CHEST AREAS THAT ARE OFTEN IGNORED.
- APPLY LIBERALLY 15 MINUTES BEFORE SUN EXPOSURE.
- REAPPLY 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 A BROAD-SPECTRUM SPF OF 15 OR HIGHER AND OTHER SUN PROTECTION MEASURES INCLUDING:
- LIMIT TIME IN THE SUN, ESPECIALLY BETWEEN 10 A.M. AND 2 P.M.
- WEAR LONG-SLEEVED SHIRTS, PANTS, HATS AND SUNGLASSES
- CHILDREN UNDER 6 MONTHS: CONSULT A PHYSICIAN

INACTIVE INGREDIENTS

NON-GMO RUBUS IDEAUS (RED RASPBERRY SEED) OIL, NON-GMO PRUNUS DOMESTICA (FRENCH PLUM SEED) OIL, ORGANIC MACADAMIA TERNIFOLIA (MACADAMIA NUT SEED) OIL, NON-GMO ALEURITES MOLUCCANA (KUKUI SEED) OIL, ORGANIC PERSEA

GRATISSIMA (AVOCADO) OIL, ORGANIC SIMMONDSIA CHINENSIS (JOJOBA SEED) OIL, ORGANIC BEESWAX, TOCOPHEROL (NON-GMO VITAMIN E FROM SUNFLOWER).
KEEP THIS PRODUCT AWAY FROM EXCESSIVE HEAT AND DIRECT SUNLIGHT

QUESTIONS OR COMMENTS?

CALL MONDAY THROUGH FRIDAY, 206-588-1573 (9 A.M. TO 5 P.M. PST)



KARI GRAN ESSENTIAL SPF SPF 28 zinc oxide lotion **Product Information** HUMAN OTC DRUG Product Type Item Code (Source) NDC:73665-101 Route of Administration **TOPICAL Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) ZINC CATION 17 g in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
RASPBERRY SEED OIL (UNII: 9S8867952A)				
PLUM SEED OIL (UNII: 67EIU8N086)				
MACADAMIA O IL (UNII: 515610SU8C)				
KUKUI NUT OIL (UNII: TP11QR7B8R)				
AVOCADO OIL (UNII: 6VNO72PFC1)				
JOJOBA OIL (UNII: 724GKU717M)				
YELLOW WAX (UNII: 2ZA36H0S2V)				
TOCOPHEROL (UNII: R0ZB2556P8)				

1	Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:73665-101-15	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/29/2020					
2	NDC:73665-101-30	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/29/2020					
3	NDC:73665-101-50	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/29/2020					

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph not final	part352	04/29/2020					

Labeler - GRAN KARI INC (028492351)

Establishment						
Name	Address	ID/FEI	Business Operations			
GRAN KARI INC		028492351	manufacture (73665-101)			

Revised: 4/2020 GRAN KARI INC