AVEENO CALM PLUS RESTORE DAILY MOISTURIZER MINERAL SUNSCREEN BROAD SPECTRUM SPF 30- titanium dioxide, zinc oxide lotion Johnson & Johnson Consumer 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.

Aveeno Protect Plus Soothe Face Mineral Sunscreen SPF 30

Drug Facts

Titanium Dioxide

Zinc Oxide

Active ingredients	Purpose	
Titanium Dioxide (5.8%)	Sunscreen	
Zinc Oxide (12.5%)	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

• On damaged or broken skin

When using this product

■ Keep out of eyes. Rinse with water to remove.

and ask a doctor if

Rash occurs

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

Directions

For sunscreen use:

- Apply generously and evenly 15 minutes before sun exposure
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating
- 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
- children under 6 months of age: Ask a doctor.

Other information

- Protect this product from excessive heat and direct sun
- May stain some fabrics

Inactive ingredients

Water, Caprylic/Capric Triglyceride, Glycerin, Ethylhexyl, Methoxycrylene, Dimethicone, Triacontanyl PVP, Glyceryl Stearate, Calcium Sodium Borosilicate, PEG-100 Stearate, Polyhydroxystearic Acid, VP/Hexadecene Copolymer, Avena Sativa (Oat) Kernel Extract, Chrysanthemum Parthenium (Feverfew) Flower/Leaf/Stem Juice, Tocopheryl Acetate, Xanthan Gum, Cetearyl Olivate, Sorbitan Olivate, Stearic Acid, Triethoxycaprylylsilane, Ethylhexylglycerin, Sodium Chloride, Phenoxyethanol, Cetearyl Alcohol, Chlorphenesin, Disodium EDTA, Aluminum Hydroxide, Iron Oxides

Ouestions?

866-428-3366; Outside US, dial collect 215-273-8755 www.aveeno.comDistributed by:

JOHNSON & JOHNSON CONSUMER INC.

Skillman, NJ 08558

PRINCIPAL DISPLAY PANEL - 48mL Carton Label

New

Aveeno R

Calm +

Restore

DAILY

MOISTURIZER

mineral sunscreen

BROAD SPECTURM

SPF 30

ZINC OXIDE

TITANIUM DIOXIDE

Sensitive Skin

Lightweight

all day moisture

FRAGRANCE FREE

SPF

30

DERMATOLOGIST RECOMMENDED BRAND

SOOTHING OAT+ FEVERFEW

1.7 FL. OZ (48 mL)





AVEENO CALM PLUS RESTORE DAILY MOISTURIZER MINERAL SUNSCREEN BROAD SPECTRUM SPF 30

titanium dioxide, zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69968-0813
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	58 mg in 1 mL	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	125 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
SORBITAN OLIVATE (UNII: MDL271E3GR)		
FERROUS OXIDE (UNII: G7036X8B5H)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)		
TANACETUM PARTHENIUM (UNII: 6GE7Z0761K)		
CETEARYL OLIVATE (UNII: 58B69Q84JO)		
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
CHLORPHENESIN (UNII: 1670DAL4SZ)		
TRIACONTANYL PVP (WP-660) (UNII: N0SS3Q238D)		

OAT (UNII: Z6J799EAJK)	
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DIMETHICONE (UNII: 92RU3N3Y10)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERIN (UNII: PDC6A3C0OX)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69968- 0813-2	1 in 1 CARTON	06/01/2023		
1		48 mL in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:69968- 0813-1	12 in 1 TRAY	06/01/2023		
2		14 mL in 1 TUBE; 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	06/01/2023	

Labeler - Johnson & Johnson Consumer Inc. (118772437)

Revised: 5/2023 Johnson & Johnson Consumer Inc.