

ROC MULTI CORREXION 5 IN 1 CHEST, NECK AND FACE SUNSCREEN BROAD SPECTRUM SPF 30- avobenzone, homosalate, octisalate, octocrylene lotion
ROC Skincare

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.

ROC MULTI CORREXION 5 IN 1 CHEST, NECK AND FACE SUNSCREEN BROAD SPECTRUM SPF 30.jpg

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



Drug Facts

Active ingredients

Avobenzone (2%), Homosalate (4%) } Sunscreen
Octisalate (4%), Octocrylene (2%) }

Purpose

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

Directions For sunscreen use: • apply generously 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 ▶

Drug Facts (continued)

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, Propylene Glycol, Glycerin, Isononyl Isononanoate, Dimethicone, Steareth-2, Ethylhexyl Palmitate, Styrene/Acrylates Copolymer, Butyrospermum Parkii (Shea) Butter, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer, Hexylresorcinol, Steareth-21, Ammonium Acryloyldimethylsulfate/VP Copolymer, Behenyl Alcohol, Phenoxyethanol, Dimethicone Crosspolymer, Ascorbyl Glucoside, Sclerotium Gum, Chlorphenesin, Fragrance, Disodium EDTA, Tocopheryl Acetate, Maltodextrin, Ethylhexylglycerin, Sodium Hydroxide, Butylene Glycol, Peucedanum Graveolens (Dill) Extract, Rubus Fruticosus (Blackberry) Leaf Extract, Xanthan Gum

Questions? Call toll-free 800-762-1964 or 215-273-8755 (collect) or visit www.rocskincare.com



4069600





OTC - PURPOSE

Active ingredients Purpose

Avobenzone 2% Sunscreen Homosalate 4% Sunscreen Octisalate 4% Sunscreen Octocrylene 2% Sunscreen

OTC - KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

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

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

INACTIVE INGREDIENTS

Water, Propylene Glycol, Glycerin, Isononyl Isononanoate, Dimethicone, Steareth-2, Ethylhexyl Palmitate, Styrene/Acrylates Copolymer, Butyrospermum Parkii (Shea) Butter, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer, Hexylresorcinol, Steareth-21, Ammonium Acryloyldimethyltaurate/VP Copolymer, Behenyl Alcohol, Phenoxyethanol, Dimethicone Crosspolymer, Ascorbyl Glucoside, Sclerotium Gum, Chlorphenesin, Fragrance, Disodium EDTA, Tocopheryl Acetate, Maltodextrin, Ethylhexylglycerin, Sodium Hydroxide, Butylene Glycol, Peucedanum Graveolens (Dill) Extract, Rubus Fruticosus (Blackberry) Leaf Extract, Xanthan Gum

QUESTIONS?

Call 1-800-RoC-1964 (1-800-762-1964); Outside US, dial collect 215-273-8755, or visit www.rocskincare.com

ROC MULTI CORREXION 5 IN 1 CHEST, NECK AND FACE SUNSCREEN BROAD SPECTRUM SPF 30

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73496-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	40 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	40 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
STEARETH-2 (UNII: V56DFE46J5)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
STYRENE/ACRYLAMIDE COPOLYMER (500000 MW) (UNII: 5Z4DPO246A)	
SHEA BUTTER (UNII: K49155WL9Y)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
HEXYLRESORCINOL (UNII: R9QTB5E82N)	
STEARETH-21 (UNII: 53J3F32P58)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
DOCOSANOL (UNII: 9G1OE216XY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
ASCORBYL GLUCOSIDE (UNII: 2V52R0NHXW)	
BETASIZOFIRAN (UNII: 2X51AD1X3T)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DILL (UNII: Y05PC4JZRH)	
RUBUS FRUTICOSUS LEAF (UNII: YQ2S06L8S9)	
XANTHAN GUM (UNII: TTV12P4NEE)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73496-003-01	1 in 1 CARTON	09/01/2015	

1	48 g in 1 JAR; 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	09/01/2015	

Labeler - ROC Skincare (117157981)

Registrant - ROC Skincare (117157981)

Establishment			
Name	Address	ID/FEI	Business Operations
Vee Pak LLC/Voyant Beauty		080578923	manufacture(73496-003)

Revised: 12/2019

ROC Skincare