AGE RENEWAL FIRMING- octinoxate, octisalate, oxybenzone, titanium dioxide, zinc oxide lotion

AMCOL Health & Beauty Solutions, Inc. DBA

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.

Drug Facts

Active ingredients

Octinoxate 6.0%

Octisalate 5.0%

Oxybenzone 4.0%

Titanium Dioxide 3.9%

Zinc Oxide 2.0%

Purpose

Sunscreen

Sunscreen

Sunscreen

Sunscreen

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 cause by the sun.

Warnings

For external use only.

Do not use on damaged or broken skin

Stop use and ask a doctor if rash occurs

When using this product keep out of eyes. Rinse with water to remove.

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

Directions

- Apply liberally 15 minutes before sun exposure
- Use a water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- Children under 6 months: Ask a doctor
- **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

Other information

• Protect the product in this container from excessive heat and direct sunlight

Inactive ingredients

Water, Glyceryl Stearate, Caprylic/Capric Triglyceride, Glycerin, Isopropyl Myristate, Octyldodecyl Neopentanoate, Cetyl Alcohol, Sodium Cetearyl Sulfate, Squalane, Dimethicone, Phenoxyethanol, Methyl Methacrylate/Glycol Dimethacrylate Crosspolymer, Cetearyl Glucoside, Xanthan Gum, Chlorphenesin, Bentonite, Retinol, Polysorbate 20, Sodium Polyacrylate, BHT, Picea Abies Wood Extract, Ethylhexylglycerin, Sodium Borate, Silica, Panthenol, Polyhydroxystearic Acid, Arginine, Tocopheryl Acetate, Alumina, Copper Tripeptide-1, Hydrolyzed Soy Protein, Glycine, Sorbitol, Ascorbic Acid, Disodium EDTA, Propyl Gallate

Distributed by:

CVS Pharmacy, Inc.

One CVS Drive

Woonsocket, RI 02895

© 2012 CVS/pharmacy

CVS.com® 1-800-SHOP CVS

Made in the U.S.A. of U.S. and foreign components

V-13649

CVS® Quality

Money Back Guarantee

FP104

M050617

Principal Display Panel - Age Renewal Firming & Hydrating Moisturizer Carton Label

CVS

pharmacy[®]

age renewal

firming & hydrating moisturizer

SPF 30

Broad Spectrum SPF 30 Sunscreen

90% saw reduction in the appearance of fine lines

With retinol SR & copper

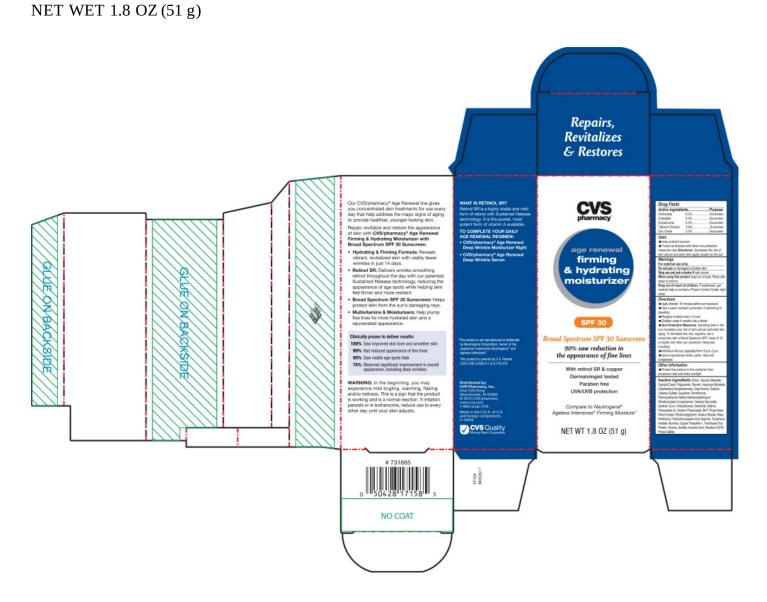
Dermatologist tested

Paraben free

UVA/UVB protection

Compare to Neutrogena®

Ageless Intensives® Firming Moisture*



Principal Display Panel - Age Renewal Firming & Hydrating Moisturizer Label

CVS pharmacy®

age renewal

firming & hydrating moisturizer

SPF 30

Broad Spectrum SPF 30 Sunscreen

90% saw reduction in the appearance of fine lines

With retinol SR & copper

Dermatologist tested
Paraben free
UVA/UVB protection
NET WET 1.8 OZ (51 g)



Broad Spectrum SPF 30 Sunscreen

90% saw reduction in the appearance of fine lines

With retinol SR & copper Dermatologist tested Paraben free UVA/UVB protection

NET WT 1.8 OZ (51 g)

DIRECTIONS: Apply liberally 15 minutes before sun exposure. Use a water resistant sunscreen if swimming or sweating. Reapply at least every 2 hours. Children under 6 months: Ask a doctor.

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.

WARNINGS: For external use only. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product keep out of eyes. Rinse with water to remove. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

ACTIVE INGREDIENTS: Octinoxate 6.0%, Octisalate 5.0%, Oxybenzone 4.0%, Titanium Dioxide 3.9%, Zinc Oxide 2.0%

This product is covered by U.S. Patents 5,851,538, 6,500,411 & 6,716,418.

Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895 © 2012 CVS/pharmacy www.cvs.com 1-800-shop-CVS

Made in the U.S.A. of U.S. and foreign components V-13649



AGE RENEWAL FIRMING

octinoxate, octisalate, oxybenzone, titanium dioxide, zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68634-063
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
octinoxate (UNII: 4Y5P7MUD51) (octinoxate - UNII:4Y5P7MUD51)	o ctino xate	60 mg in 1 g	
octisalate (UNII: 4X49 Y0596W) (octisalate - UNII:4X49 Y0596W)	o ctisa late	50 mg in 1 g	
oxybenzone (UNII: 9500S7VE0Y) (oxybenzone - UNII:9500S7VE0Y)	o xybe nz o ne	40 mg in 1 g	
titanium dioxide (UNII: 15FIX9V2JP) (titanium dioxide - UNII:15FIX9V2JP)	titanium dio xide	39 mg in 1 g	
zinc oxide (UNII: SOI2LOH54Z) (zinc oxide - UNII:SOI2LOH54Z)	zinc oxide	20 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
water (UNII: 059QF0KO0R)		
glyceryl monostearate (UNII: 230 O U9 XXE4)		
medium-chain triglycerides (UNII: C9H2L21V7U)		

glycerin (UNII: PDC6A3C0OX)	
isopropyl myristate (UNII: 0 RE8 K4LNJS)	
cetyl alcohol (UNII: 936JST6JCN)	
octyldodecyl neopentanoate (UNII: X8725R883T)	
sodium cetostearyl sulfate (UNII: 7ZBS06BH4B)	
dimethicone (UNII: 92RU3N3Y1O)	
squalane (UNII: GW89575KF9)	
phenoxyethanol (UNII: HIE492ZZ3T)	
methyl methacrylate/glycol dimethacrylate crosspolymer (UNII: EG97988M5Q)	
cetearyl glucoside (UNII: 09FUA47KNA)	
xanthan gum (UNII: TTV12P4NEE)	
chlorphenesin (UNII: I670 DAL4SZ)	
bentonite (UNII: A3N5ZCN45C)	
retinol (UNII: G2SH0 XKK91)	
polysorbate 20 (UNII: 7T1F30V5YH)	
sodium polyacrylate (8000 mw) (UNII: 285CYO341L)	
butylated hydroxytoluene (UNII: 1P9 D0 Z171K)	
ethylhexylglycerin (UNII: 147D247K3P)	
picea abies wood (UNII: 72GZ8K8996)	
sodium borate (UNII: 91MBZ8H3QO)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
panthenol (UNII: WV9CM0O67Z)	
polyhydroxystearic acid (2300 mw) (UNII: YXH47AOU0F)	
arginine (UNII: 94ZLA3W45F)	
.alphatocopherol acetate, DL- (UNII: WR1WPI7EW8)	
aluminum oxide (UNII: LMI26O6933)	
prezatide copper (UNII: 6BJQ43T1I9)	
glycine (UNII: TE7660XO1C)	
sorbitol (UNII: 506T60A25R)	
ascorbic acid (UNII: PQ6CK8PD0R)	
edetate disodium (UNII: 7FLD91C86K)	
propyl gallate (UNII: 8D4SNN7V92)	

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68634-063-01	1 in 1 CARTON	10 / 0 1 / 20 14	
1		51 g in 1 BOTTLE; 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	10/01/2014		

Labeler - AMCOL Health & Beauty Solutions, Inc. DBA (872684803)

Establishment

Name	Address	ID/FEI	Business Operations
AMCOL Health & Beauty Solutions, Inc. DBA		872684803	MANUFACTURE(68634-063), PACK(68634-063), LABEL(68634-063), ANALYSIS(68634-063)

Revised: 10/2016 AMCOL Health & Beauty Solutions, Inc. DBA