

NATURAL SPF 28- zinc oxide 11.6%, titanium dioxide 0.67% cream
CoValence, 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.

Drug Facts

Active Ingredient(s):

11.6% Zinc Oxide, 0.67% Titanium Dioxide

Purpose:

Sunscreen

Warnings: (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 a rash occurs.

Directions:

- Apply liberally 15 minutes before sun exposure.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply 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 a broad spectrum SPF 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-sleeve shirts, pants, hats and sunglasses.
- Children under 6 months: Ask a doctor.

Inactive Ingredients:

Alcohol, Allantoin, Aloe Barbadensis Leaf Juice Powder, Alumina, Aqua (Water), Caprylic/Capric Triglyceride, Cetyl Alcohol, Ceteryl Glucoside, Citric Acid, Coco-Caprylate/Caprates, Dicaprylyl Ether, Fructooligosaccharides (D-Beta), Gluconolactone, Glycerin, Glycine Soja (Soybean) Oil, Glyceryl Isostearate, Hamamelis Virginiana (Witch Hazel) Water, Isononyl Isononanoate, Magnesium Aluminum Silicate, Polyhydroxystearic Acid, Polyglyceryl-6 Polyricinoleate, Polysorbate 60, Potassium Sorbate, Simethicone, Sodium Benzoate, Squalane, Tocopheryl Acetate (D-alpha), Trisodium

Ethylenediamine, Xanthan Gum

Other Information:

Protect this product from excessive heat and direct sun.

PDP



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Product Name: Natural SPF 28

Drug Facts	NDC 66915 604 02
Active Ingredient(s): 11.6% Zinc Oxide, 0.67% Titanium Dioxide	Purpose: Sunscreen
Uses: <ul style="list-style-type: none">• Helps prevent sunburn.• If used as directed with other sun protection measures (see <i>Directions</i>), decreases the risk of skin cancer and early skin aging caused by the sun.	
Warnings: <ul style="list-style-type: none">• 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: <ul style="list-style-type: none">• Apply liberally 15 minutes before sun exposure.• Use a water resistant sunscreen if swimming or sweating.• Reapply 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 a broad spectrum SPF 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-sleeve shirts, pants, hats and sunglasses.• Children under 6 months: Ask a doctor.	
Inactive Ingredients: Alcohol, Allantoin, Aloe Barbadensis Leaf Juice Powder*, Alumina, Aqua (Water), Caprylic/Capric Triglyceride, Cetyl Alcohol, Cetearyl Glucoside, Citric Acid, Coco-Caprylate/Caprate, Dicaprylyl Ether, Fructooligosaccharides (D-Beta), Gluconolactone, Glycerin, Glycine Soja (Soybean) Oil, Glyceryl Isostearate, Hamamelis Virginiana (Witch Hazel) Water, Isononyl Isononanoate, Magnesium Aluminum Silicate, Polyhydroxystearic Acid, Polyglyceryl-6 Polyridinoleate, Polysorbate 60, Potassium Sorbate, Simethicone, Sodium Benzoate, Squalane, Tocopheryl Acetate (D-alpha), Trisodium Ethylenediamine, Xanthan Gum	
Other Information: Protect this product from excessive heat and direct sun.	

NATURAL SPF 28

zinc oxide 11.6%, titanium dioxide 0.67% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66915-604
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	.116 g in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	.0067 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	1 g in 1 g
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	1 g in 1 g
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	1 g in 1 g
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	1 g in 1 g
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	1 g in 1 g
POLYSORBATE 60 (UNII: CAL22UVI4M)	1 g in 1 g
GLYCERIN (UNII: PDC6A3C0OX)	1 g in 1 g
SQUALANE (UNII: GW89575KF9)	1 g in 1 g
POLYGLYCERYL-6 DIOLEATE (UNII: 062SZD3F3X)	1 g in 1 g
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	1 g in 1 g
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	1 g in 1 g
XANTHAN GUM (UNII: TTV12P4NEE)	1 g in 1 g
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	1 g in 1 g
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	1 g in 1 g
ALUMINUM OXIDE (UNII: LM26O6933)	1 g in 1 g
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	1 g in 1 g
SOYBEAN OIL (UNII: 241ATL177A)	1 g in 1 g
ALOE VERA LEAF (UNII: ZY81Z83H0X)	1 g in 1 g
DIMETHICONE (UNII: 92RU3N3Y1O)	1 g in 1 g
ALLANTOIN (UNII: 344S277G0Z)	1 g in 1 g
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	1 g in 1 g
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22HB34H9Q)	1 g in 1 g
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	1 g in 1 g
POPULUS TREMULOIDES BARK (UNII: 5543O0CEID)	1 g in 1 g
DICAPRYLYL ETHER (UNII: 77JZM5516Z)	1 g in 1 g
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	1 g in 1 g
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	1 g in 1 g
GLUCONOLACTONE (UNII: WQ29KQ9POT)	1 g in 1 g
LONICERA CAPRIFOLIUM FLOWER (UNII: 5N1WD9784U)	1 g in 1 g
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)	1 g in 1 g
TROPOLONE (UNII: 7L6DL16P1T)	1 g in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66915-604-02	200000 g in 1 DRUM		
2	NDC:66915-604-24	1 in 1 PACKAGE		
2	NDC:66915-604-07	100 g in 1 BOTTLE		
3	NDC:66915-604-22	1 in 1 PACKAGE		
3	NDC:66915-604-08	70 g in 1 TUBE		
4	NDC:66915-604-25	1 in 1 PACKAGE		

4	NDC:66915-604-12	120 g in 1 TUBE		
5	NDC:66915-604-14	30 g in 1 BOTTLE		
6	NDC:66915-604-16	65 g in 1 JAR		
7	NDC:66915-604-17	135 g in 1 JAR		
8	NDC:66915-604-23	1 in 1 PACKAGE		
8	NDC:66915-604-20	70 g in 1 TUBE		
9	NDC:66915-604-21	30 g in 1 BOTTLE		
10	NDC:66915-604-30	30 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/02/2013	

Labeler - CoValence, Inc. (070653204)

Establishment

Name	Address	ID/FEI	Business Operations
CoValence, Inc		070653204	manufacture(66915-604)

Revised: 12/2013

CoValence, Inc.