ULTRA UV DEFENSE SPF 30- zinc oxide cream
Jenelt Cosmetics

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 OTC #610; Ultra UV Defense SPF 30

Active Ingredient:

Zinc Oxide 13.5%

Purpose: Sunscreen

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

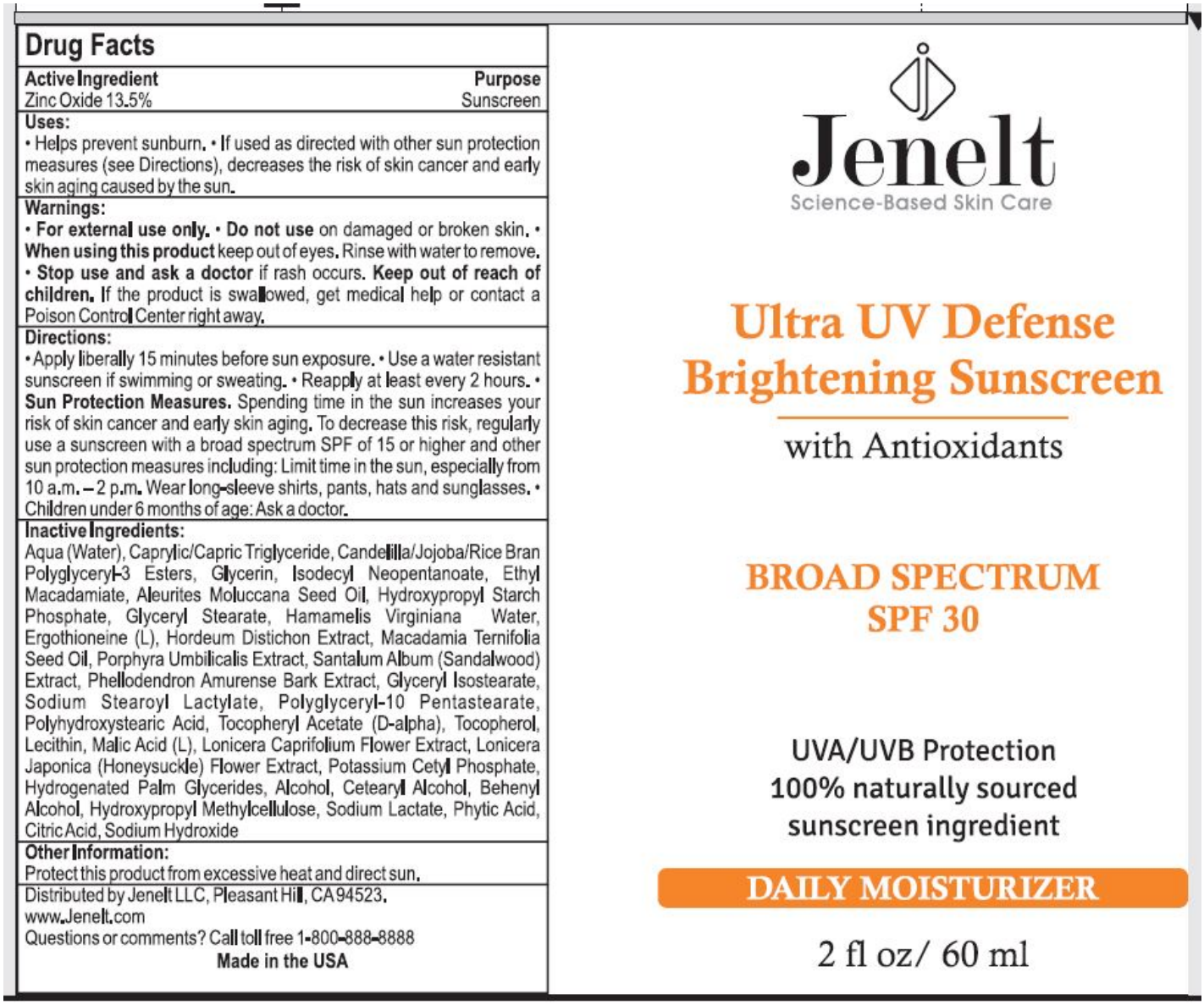
Uses:
- Helps prevent sunburn.
- If used as directed with other sun protection measures (see *Directions*), decreases the risk of skin cancer and early skin aging caused by the sun.

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.
- **Keep out of reach of children.** If the product is 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.
- **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: Aqua (Water), Caprylic/Capric Triglyceride, Candelilla/Jojoba/Rice Bran Polyglyceryl-3 Esters, Glycerin, Isodecyl Neopentanoate, Ethyl Macadamiate, Aleurites Moluccana Seed Oil, Hydroxypropyl Starch Phosphate, Glyceral Stearate, Hamamelis Virginiana (Witch Hazel) Water, Ergothioneine (L), Hordeum Distichon (Barley) Extract, Macadamia Ternifolia Seed Oil, Porphyra Umbilicalis (Red Algae) Extract, Santalum Album (Sandalwood) Extract, Phellodendron Amurense Bark Extract, Glyceryl Isostearate, Sodium Stearoyl Lactylate, Polyglyceryl-10 Pentastearate, Polyhydroxystearic Acid, Tocopheryl Acetate (D-alpha), Tocopherol (D-alpha), Lecithin, Malic Acid (L) Lonicera Caprifolium (Honeysuckle) Flower Extract, Lonicera Japonica (Honeysuckle) Flower Extract, Potassium Cetyl Phosphate, Hydrogenated Palm Glycerides, Alcohol, Cetearyl Alcohol, Behenyl Alchohol, Hydroxypropyl Methylcellulose, Sodium Lactate, Phytic Acid, Citric Acid, Sodium Hydroxide

Other Information:
- Protect this product from excessive heat and direct sun.



ULTRA UV DEFENSE SPF 30

zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58469-6100(NDC:66915-610)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.135 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)	

ETHYL MACADAMIATE (UNII: ANA2NCS6V1)	
KUKUI NUT OIL (UNII: TP11QR7B8R)	
HAMAMELIS VIRGINIANA LEAF WATER (UNII: 8FP93ED6H2)	
ERGOTHIONEINE (UNII: BDZ3DQM98W)	
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
BARLEY (UNII: 5PWM7YLI7R)	
MACADAMIA OIL (UNII: 515610SU8C)	
PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)	
SANDALWOOD (UNII: 3641YW25N2)	
PHELLODENDRON AMURENSE BARK (UNII: PBG27B754G)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)	
POLYGLYCERIN-10 (UNII: P9060O936A)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
TOCOPHEROL (UNII: R0ZB2556P8)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
MALIC ACID (UNII: 817L1N4CKP)	
LONICERA CAPRIFOLIUM FLOWER (UNII: 5N1WD9784U)	
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q)	
ALCOHOL (UNII: 3K9958V90M)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DOCOSANOL (UNII: 9G1OE216XY)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
PHYTIC ACID (UNII: 7IGF0S7R8I)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58469-6100-1	60 g in 1 TUBE; Type 0: Not a Combination Product	03/26/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/26/2014	

Labeler - Jenelt Cosmetics (078802794)

Registrant - CoValence Laboratories (070653204)

Establishment

Name	Address	ID/FEI	Business Operations
CoValence Laboratories		070653204	manufacture(58469-6100)

Revised: 11/2015

Jenelt Cosmetics