

**COVERGIRL VITALIST HEALTHY FOUNDATION WITH VITAMINS PLUS
ENSULIZOLE SUNSCREEN BROAD SPECTRUM SPF 20 (ALL SHADES) -
ensulizole liquid
Noxell Corporation**

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

Ensulizole 3%.

Purpose

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**
- **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 product is swallowed, get medical help or contact a Poison Control Center right away

Directions

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use 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 sun, especially from 10 a.m. – 2 p.m.

- wear long-sleeved shirts, pants, hats, and sunglasses
- children under 6 months: ask a doctor

Other information

- protect this product from excessive heat and direct sun

Inactive ingredients

Water, cyclopentasiloxane, propylene glycol, glycerin, titanium dioxide, dimethicone, talc, aluminum starch octenylsuccinate, peg/ppg-18/18 dimethicone, pvp, sodium chloride, phenoxyethanol, sodium hydroxide, trihydroxystearin, arachidyl behenate, caprylyl glycol, 1,2-hexanediol, methicone, fragrance, sodium benzoate, silica, acrylonitrile/methyl methacrylate/vinylidene chloride copolymer, synthetic wax, polyglyceryl-4 isostearate, hexyl laurate, cetyl peg/ppg-10/1 dimethicone, tocopheryl acetate, panthenol, niacinamide, ethylene brassylate, behenic acid, polyethylene, isopropyl titanium triisostearate, iron oxides

Questions?

Call 1-800-426-8374

MADE IN USA OF US & IMPORTED PARTS

COTYUS LLC, NEW YORK, NY 10118

Principal Display Panel - Covergirl Vitalist Healthy Elixir Label

COVERGIRL

vitalist

HEALTHY

ELIXIR

FOUNDATION WITH **VITAMINS +**
ENSULIZOLE SUNSCREEN
BROAD SPECTRUM SPF 20

705

30 mL (1 FL OZ)



COVERGIRL

**VITALIST
HEALTHY ELIXIR**

E B3 B5



COVERGIRL VITALIST HEALTHY FOUNDATION WITH VITAMINS PLUS ENSULIZOLE SUNSCREEN BROAD SPECTRUM SPF 20 (ALL SHADES)

ensulizole liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:22700-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ENSULIZOLE (UNII: 9YQ9DI1W42) (ENSULIZOLE - UNII:9YQ9DI1W42)	ENSULIZOLE	3 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TALC (UNII: 7SEV7J4R1U)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ006294)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

SODIUM HYDROXIDE (UNII: 55X04QC32I)
TRIHYDROXYSTEARIN (UNII: 06YD7896S3)
ARACHIDYL BEHENATE (UNII: 9G00Q0O2NS)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
METHICONE (20 CST) (UNII: 6777U11MKT)
SODIUM BENZOATE (UNII: OJ245FE5EU)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PANTHENOL (UNII: WW9CM0O67Z)
NIACINAMIDE (UNII: 25X51I8RD4)
ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD)
BEHENIC ACID (UNII: H390488X0A)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
ISOPROPYL TITANIUM TRIISOSTEARATE (UNII: 949E3KB1I)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:22700-200-30	30 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/2017	

Labeler - Noxell Corporation (003082997)

Registrant - COTY US LLC (039056361)

Establishment

Name	Address	ID/FEI	Business Operations
Noxell Corporation		003082997	manufacture(22700-200)