ULTA SPF 45- zinc oxide powder
Prime Enterprises, 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.

Ulta Beauty Mineral Hair & Scalp Powder Broad Spectrum SPF 45

Active ingredients

Zinc Oxide 25%

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

Do not use on damaged or broken skin

When using this product

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

Stop use and ask a doctor

Stop use and ask a doctor if rash occurs

Keep out of reach of children.

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.

use a water resistant sunscreen if swimming or sweating.

reapply at least every 2 hours.

Sunscreen 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 10am - 2pm.

wear long-sleeve shirts, pants, hats, and sunglasses

children under 6 months: ask a doctor.

Inactive ingredients

Calcium Aluminum Borosilicate, Silica, Nylon-6/12, Triethoxycaprylylsilane, Olive Glycerides, Ascorbyl Palmitate, Iron Oxides, Ceramide NP

Other information

protect this product from excessive heat and direct sun.

may stain some fabrics or surfaces.

Questions or comments?

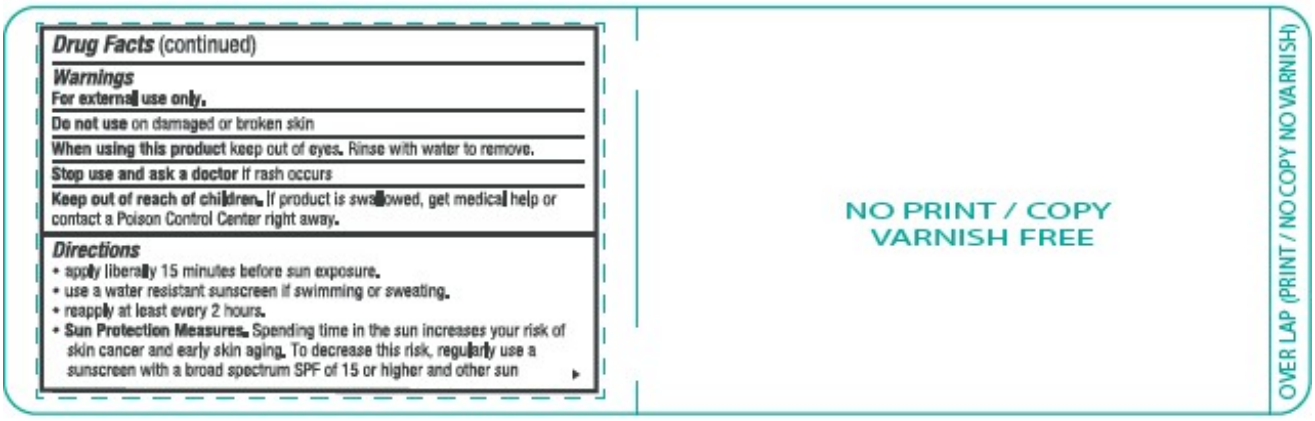
Call 1-866-983-8582

Ulta Beauty Mineral Hair & Scalp Powder Broad Spectrum SPF 45

Front Back

Inside Print - PANEL 2

5.04″



Surface Print - PANEL 3

5.04″

ULTA SPF 45

zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0393
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.25 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
CERAMIDE NP (UNII: 4370DF050B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
NYLON 612 (MW 14000) (UNII: E7LN56Z3RX)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

Product Characteristics

Color	yellow (Beige)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0393-2	20 g in 1 BOTTLE; Type 0: Not a Combination Product	03/04/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/04/2021	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0393) , pack(58443-0393) , manufacture(58443-0393) , analysis(58443-0393)

Revised: 8/2021

Prime Enterprises, Inc.