INVINCIBLE SETTING POWDER SPF 45 LIGHT- zinc oxide powder TAYLOR JAMES, LTD.

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.

Invincible Setting Powder SPF 45 Light

Active ingredients Purpose

Zinc Oxide 24.5% 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.

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

Stop use and ask a doctor if rash occurs

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.

Directions

- apply generously and evenly 15 minutes before sun exposure
- reapply
- after 40 minutes of swimming or sweating
- immediately after towel drying
- 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 value of 15 or higher and other sun protections measures including:
- Limit time in the sun, especially from 10a.m. -2p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses
- Children under 6 months: Ask a doctor

Inactive Ingredients

Calcium Aluminum Borosilicate, Silica, Polymethyl Methacrylate, Ethylhexylglycerin, Triethoxycaprylysilane, Nylon-6/12, Sodium Dehydroacetate, Olive Glycerides, Ascorbyl Palmitate, Ceramide 3. May contain +/- Iron Oxides (CI 77492, CI 77491, CI 77499), Titanium Dioxide (CI 77891)

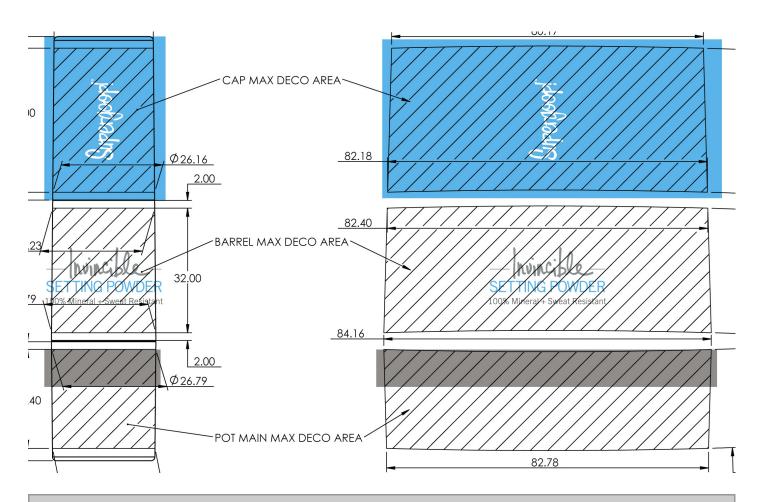
Invincible Setting Powder SPF 45

100% Mineral + Sweat resistant

Light

0.15 oz./ 4.25 g





INVINCIBLE SETTING POWDER SPF 45 LIGHT

zinc oxide powder

Dro	duct	Infor	mation
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:75936-146

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII: SOI2LOH54Z)	ZINC OXIDE	24 5 g in 100 g

Inactive Ingredients			
Ingredient Name	Strength		
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8 A35M0)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
TRIETHO XYCAPRYLYLSILANE (UNII: LDC331P08E)			
SO DIUM DEHYDRO ACETATE (UNII: 8 W46 YN9 71G)			
ASCORBYL PALMITATE (UNII: QN83US2B0N)			
CERAMIDE 3 (UNII: 4370 DF0 50 B)			

Other Ingredients			
Ingredient Kind	Ingredient Name	Quantity	
May contain	FERRIC OXIDE RED (UNII: 1K09F3G675)		
May contain	FERRIC OXIDE YELLOW (UNII: EX438O2MRT)		
May contain	FERROSOFERRIC OXIDE (UNII: XM0 M87F357)		
May contain	TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:75936-146-02	1 in 1 BOX	0 1/15/20 18		
NDC:75936-146-01	4.25 g in 1 PACKAGE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	0 1/15/20 18	

Labeler - TAYLORJAMES, LTD. (033381850)

Establishment				
Name	Address	ID/FEI	Business Operations	
Kolmar Laboratories, Inc.		001535103	manufacture(75936-146)	

Revised: 1/2018 TAYLOR JAMES, LTD.