INVINCIBLE SETTING POWDER SPF 45 TRANSLUCENT- 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 Translucent

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** DSpending 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)

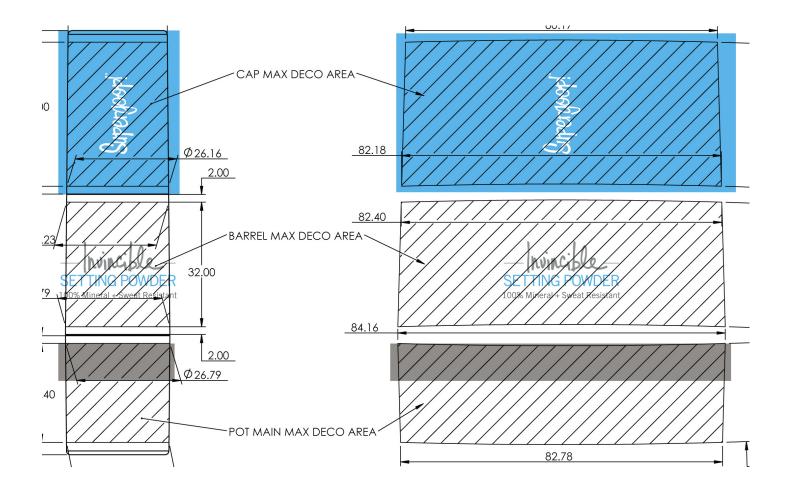
Invincible Setting Powder SPF 45

100% Mineral + Sweat resistant

Translucent

0.15 oz./ 4.25 g







INVINCIBLE SETTING POWDER SPF 45 TRANSLUCENT

zinc oxide powder

Product Information						
Product T ype	HUMAN OTC DRUG	Item Code (Source)		NDC	NDC:75936-145	
Route of Administration	TOPICAL					
Active Ingredient/Active N	Aninty					
Ū	gredient Name		Basis of Stren	gth	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z)		ZINC OXIDE		24.5 g in 100 g		
Inactive Ingredients						
	Ingredient Name				Strength	
CALCIUM ALUMINUM BOROSIL	ICATE (UNII: 3JRB8A35M0)					
SILICON DIO XIDE (UNII: ETJ7Z6)	XBU4)					
)				
POLY(METHYL METHACRYLAT	E; 450000 MW) (UNII: Z4/INN14J1	-)				

so	DIUM DEHYDRO A	CETATE (UNII: 8 W46 YN9 71G)		
AS	CORBYL PALMIT	ATE (UNII	QN83US2B0N)		
CE	RAMIDE 3 (UNII: 4)	370 DF0 50 I	3)		
Ot	ther Ingredien	ts			
Ingredient Kind		ind	Ingredient Na	Quantity	
Mag	ay contain FERRIC O XIDE RED (UNII: 1K09F3G675)				
Mag	May containFERRIC OXIDE YELLOW (UNII: EX43802MF		T)		
Mag	y contain		FERROSOFERRIC OXIDE (UNII: XM0 M87F35	57)	
	y contain y contain		FERROSOFERRIC OXIDE (UNII: XM0 M8 7F35 TITANIUM DIOXIDE (UNII: 15FIX9 V2JP)	.7)	
Mag			3	.7)	
May Pa	y contain		3	⁵⁷⁾ Marketing Start Date	Marketing End Date
May Pa #	y contain	1 in 1 BO X	TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) Package Description		Marketing End Date
May Pa #	y contain tckaging Item Code NDC:75936-145-02		TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) Package Description	Marketing Start Date 01/15/2018	Marketing End Date
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May Pa # 1 P 1 P	y contain Ickaging Item Code NDC:75936-145-02 NDC:75936-145-01	4.25 g in 1	TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) Package Description A PACKAGE; Type 0: Not a Combination Product	Marketing Start Date 01/15/2018	Marketing End Date
May Pa # 1 M 1 M	y contain tckaging Item Code NDC:75936-145-02	4.25 g in 1	TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) Package Description A PACKAGE; Type 0: Not a Combination Product	Marketing Start Date 01/15/2018	Marketing End Date

Labeler - TAYLORJAMES, LTD. (033381850)

Establishment

Name	Address	ID/FEI	Business Operations
Kolmar Laboratories, Inc.		001535103	manufacture(75936-145)

Revised: 2/2018

TAYLOR JAMES, LTD.