

ZINC OXIDE- zinc oxide spray, suspension
Kindred Bravely

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.

Active Ingredient

Zinc Oxid 25%

Purpose

Skin Protectant

Uses

Helps treat and prevent diaper rash
Protects minor skin irritation associated with diaper rash
Helps seal out wetness

Warnings

For external use only

When using this product

avoid contact with eyes

Stop use and ask a doctor

if symptoms last more than 7 days or clears up and occurs again within a few days.

Keep out of reach of children

If swallowed get medical help or contact a Poison Control Center right away.

Directions

Shake well before use
Change wet and soiled diapers promptly, cleanse the diaper area, and allow to dry
Spray 4-6 inches away from skin.
Spray product liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged
No need to rub in.

Inactive Ingredients

Aqua (Water), Helianthus annuus (Sunflower) Oil, Simmondsia chinensis (Jjoba) Seed Oil, Ricinus communis (Castor) Seed Oil, Butyrospermum parkii (Shea) Butter, Cetearyl Alcohol, Cetearyl Glucoside, Organic Aloe barbadensis (Aloe vera) Leaf Juice, Glyceryl Caprylate, Caprylhydroxamic Acid, Xanthan Gum.

Distributed by Sensible

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ZINC OXIDE

zinc oxide spray, suspension

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82751-103	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	250 mg in 1 mL		
Inactive Ingredients				
Ingredient Name	Strength			
CASTOR OIL (UNII: D5340Y2I9G)				
SHEA BUTTER (UNII: K49155WL9Y)				
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)				
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)				
WATER O-18 (UNII: 7QV8F8BYNJ)				
SUNFLOWER OIL (UNII: 3W1JG795YI)				
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)				
XANTHAN GUM (UNII: TTV12P4NEE)				
JOJOBA OIL (UNII: 724GKU717M)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82751-103-01	89 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/30/2022	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	06/14/2022		

Labeler - Kindred Bravely (085227654)

Establishment			
Name	Address	ID/FEI	Business Operations
Royal Labs Natural Cosmetics		197478480	manufacture(82751-103)

Revised: 5/2022

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