

SELAN PLUS ZINC OXIDE- selan plus zinc oxide cream

PJ Noyes Co. 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.

Selan Plus Zinc Oxide

Active Ingredients

Dimethicone 2.1%

Zinc Oxide 2%

Purpose

Skin Protectant

Uses

- Helps treat and prevent diaper rash
- Protects chaged skin or minor skin irritation due to diaper rash and helps seal out wetness

Warnings

For external use only

When using this product

- avoid contact with the eyes

Stop use and ask a doctor if

- condition worsens or does not improve within 7 days

Keep out of reach of children.

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

Directions

- apply cream liberally as often as necessary
- change wet and soiled diapers promptly
- cleanse the diaper area, and allow to dry
- apply cream with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged

Other Information:

Store at room temperature

Purified Water USP, Cetyl Alcohol, Sorbitol USP, Glycerol Monostearate, Sodium Lauryl Sulfate, Lanolin USP, Methylparaben, Fragrance, Quaternium-15, Propylparaben.

Image of 4oz tube
SelanTUBEimage.jpg



Image of 16oz jar



Image of 8ml packet



SELAN PLUS ZINC OXIDE

selan plus zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0159-2200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	2 g in 100 g
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	2.1 in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LANOLIN (UNII: 7EV65EAW6H)	
SORBITOL (UNII: 506T60A25R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
QUATERNIUM-15 (UNII: E40U03LEM0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0159-2200-04	117 g in 1 TUBE		
2	NDC:0159-2200-01	8.1 g in 1 PACKET		
3	NDC:0159-2200-17	458 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	08/29/1997	

Labeler - PJ Noyes Co. Inc. (018927392)

Establishment

Name	Address	ID/FEI	Business Operations
PJ Noyes Co. Inc.		018927392	manufacture(0159-2200) , label(0159-2200) , pack(0159-2200)