SELAN PLUS ZINC OXIDE- selan plus zinc oxide cream Trividia Manufacturing Solutions, 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, Propylparaben.

Image of 4oz tube

SelanZinc4ozTube.jpg



Image of 16oz jar

SelanZinc16ozJar.jpg

NET WT. 16 OZ. (453.6g)



Non-greasy barrier cream for treatment and prevention of diaper rash and pressure ulcers Indications: For the treatment and prevention of rashes, excoriations and stage one pressure ulcers caused by incontinence, perspiration or heat. 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.

Poison Control Center right away.

Directions

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

Other information: Store at room temperature

Inactive ingredients:
Purified Water USP, Cetyl Alcohol, Sorbitol
USP, Glycerol Monostearate, Sodium Lauryl
Sulfate, Lanolin USP, Methylparaben,
Fragrance, Propylbaraben.



NDC 0159-2200-17

SPANAmerica

Span-America Medical Systems, Inc.

Distributed by:

70 Commerce Center Greenville, SC 29615 800/888-6752

Image of 8ml packet SelanZinc8mlPacket.jpg



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: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	2.1 in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
CETYL ALCOHOL (UNII: 936JST6JCN)			
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)			
LANOLIN (UNII: 7EV65EAW6H)			
SORBITOL (UNII: 506T60A25R)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
METHYLPARABEN (UNII: A218C7H19T)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0159-2200- 04	117 g in 1 TUBE; Type 0: Not a Combination Product	08/29/1997	
2	NDC:0159-2200- 01	8.1 g in 1 PACKET; Type 0: Not a Combination Product	08/29/1997	
3	NDC:0159-2200- 17	458 g in 1 JAR; Type 0: Not a Combination Product	08/29/1997	

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

Labeler - Trividia Manufacturing Solutions, Inc (018927392)

Establishment			
Name	Address	ID/FEI	Business Operations
Trividia Manufacturing Solutions, Inc		018927392	manufacture(0159-2200) , label(0159-2200) , pack(0159-2200)

Revised: 3/2021 Trividia Manufacturing Solutions, Inc