ZINC OXIDE - zinc oxide ointment
Sion Biotext Medical 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.

Zinc Oxide Ointment

Active Ingredient	Purpose
Zinc Oxide (1.8% w/w)	Skin Protectant

Uses:

- Helps treat and prevent diaper rash
- Temporarily protects
- minor cuts
- scrapes and
- burns
- dries the oozing and weeping of
- poison ivy
- poison oak
- poison sumac

Warnings:

For External Use Only.

When using this product:

Do not get in eyes.

Stop use and ask a doctor if:

- condition worsens
- symptoms last more than 7 days or clear up and occur again in a few days, consult a physician

Keep out of reach of children.

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

Directions:

For skin protectant:

- Apply liberally as needed

For diaper Rash:

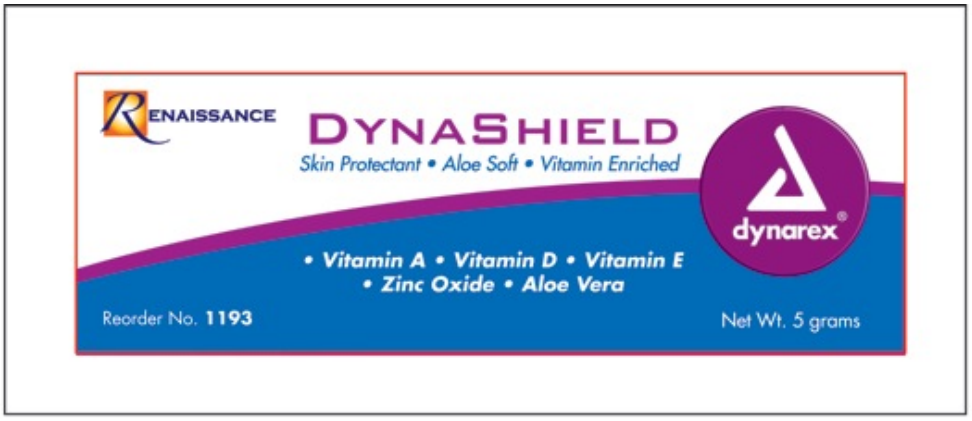
- change wet and soiled diapers promptly
- allow to dry
- apply ointment liberally with each diaper change

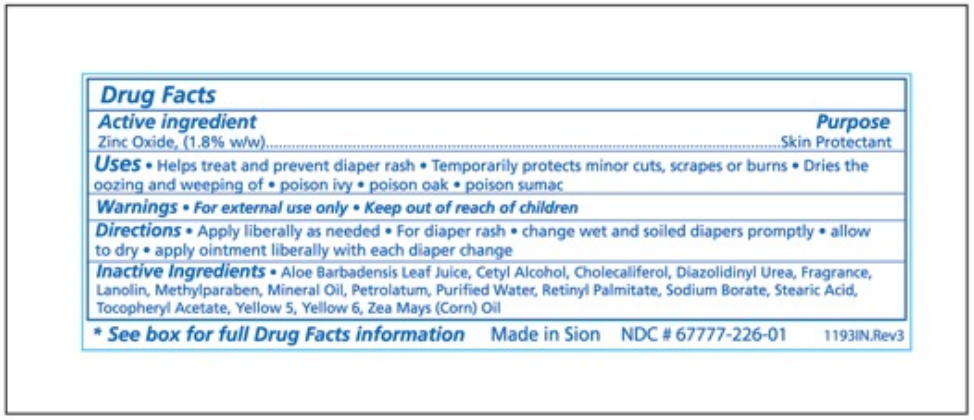
Other information:

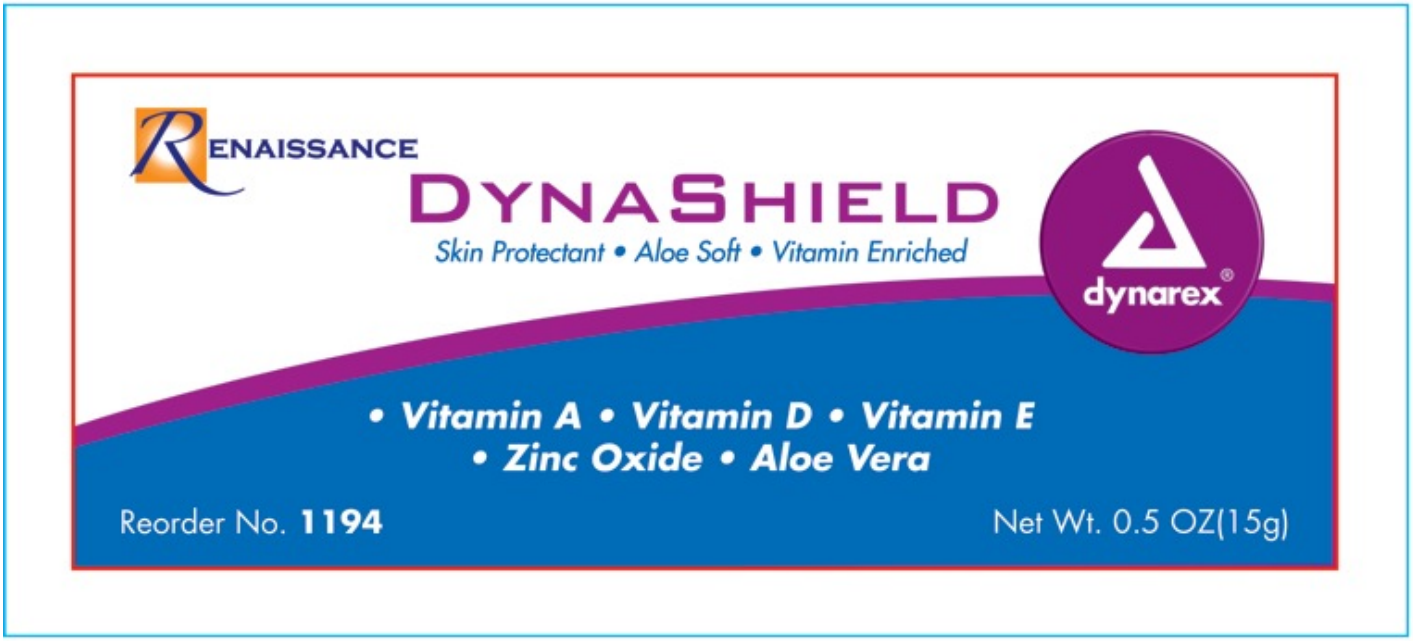
- Store at room temperature

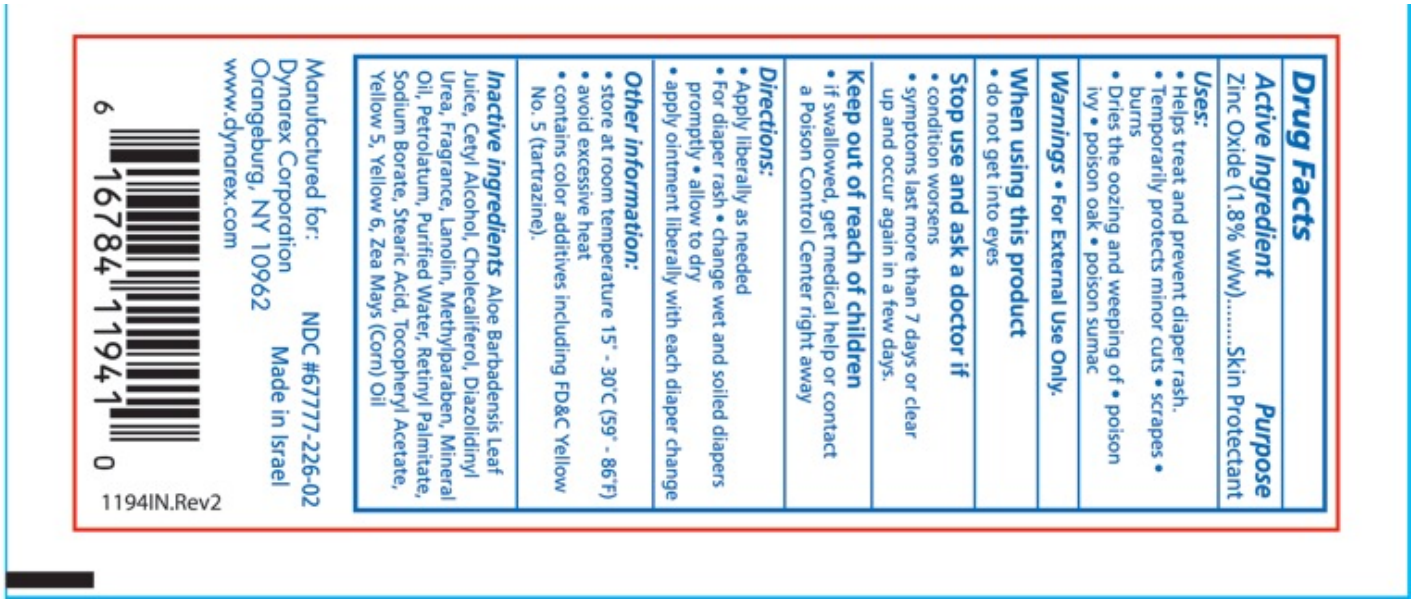
- avoid excessive heat
- contains color additives including FDC yellow # 5

Principal Display Panel









Zinc Oxide Ointment

ZINC OXIDE

zinc oxide ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68786-226
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	1.8 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIAZOLIDINYLUREA (UNII: H5RIZ3MPW4)	
LANOLIN (UNII: 7EV65EAW6H)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
CORN OIL (UNII: 8470G57WFM)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68786-226-01	6 in 1 CASE		
1		144 in 1 BOX		
1		5 g in 1 PACKET		
2	NDC:68786-226-02	6 in 1 CASE		
2		36 in 1 BOX		
2		15 g in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/01/2010	

Labeler - Sion Biotext Medical Ltd (532775194)

Registrant - Dynarex Corporation (008124359)

Establishment

Name	Address	ID/FEI	Business Operations
Sion Biotext Medical Ltd		532775194	manufacture

Revised: 1/2010 Sion Biotext Medical Ltd