

**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.*

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**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:

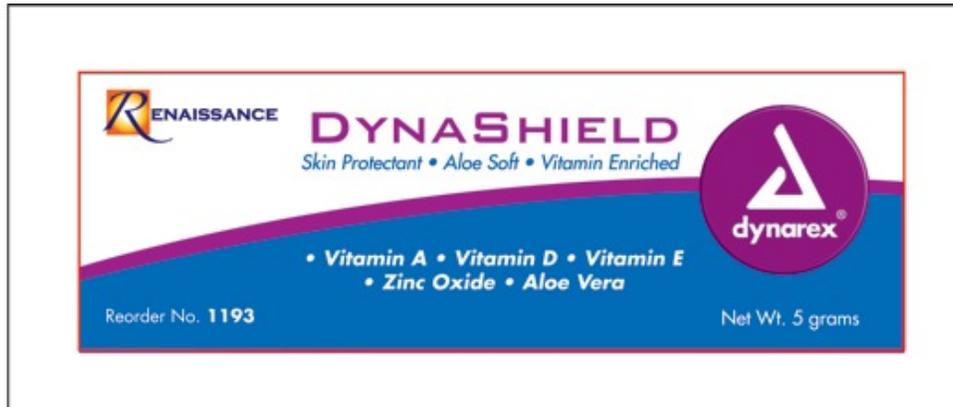
- change wet and soiled diapers promptly
- allow to dry
- apply ointment liberally with each diaper change

**Other information:**

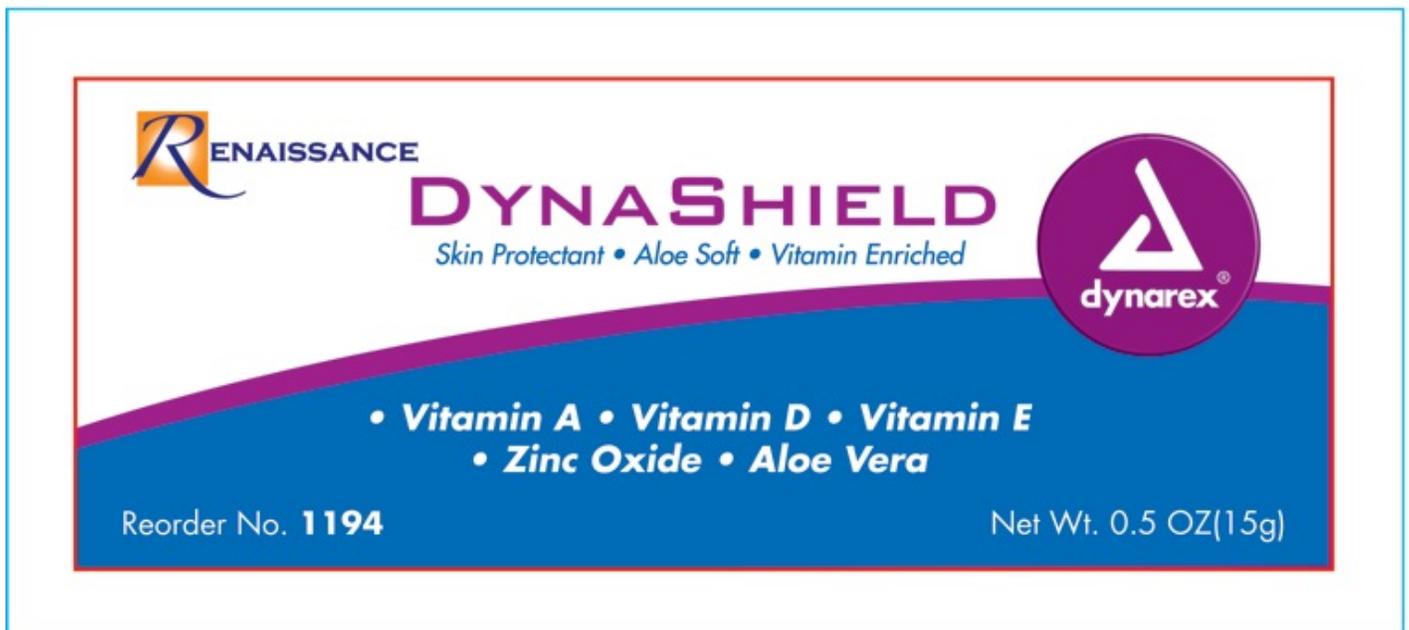
- Store at room temperature

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

**Principal Display Panel**



<b>Drug Facts</b>	
<b>Active ingredient</b> Zinc Oxide, (1.8% w/w)	<b>Purpose</b> Skin Protectant
<b>Uses</b> • Helps treat and prevent diaper rash • Temporarily protects minor cuts, scrapes or burns • Dries the oozing and weeping of • poison ivy • poison oak • poison sumac	
<b>Warnings</b> • For external use only • Keep out of reach of children	
<b>Directions</b> • Apply liberally as needed • For diaper rash • change wet and soiled diapers promptly • allow to dry • apply ointment liberally with each diaper change	
<b>Inactive Ingredients</b> • Aloe Barbadosensis Leaf Juice, Cetyl Alcohol, Cholecaliferol, Diazolidinyl Urea, Fragrance, Lanolin, Methylparaben, Mineral Oil, Petrolatum, Purified Water, Retinyl Palmitate, Sodium Borate, Stearic Acid, Tocopheryl Acetate, Yellow 5, Yellow 6, Zea Mays (Corn) Oil	
* See box for full Drug Facts information    Made in Sion    NDC # 67777-226-01    1193IN.Rev3	



<b>Drug Facts</b>
<p><b>Active Ingredient Purpose</b> Zinc Oxide (1.8% w/w).....Skin Protectant</p>
<p><b>Uses:</b></p> <ul style="list-style-type: none"> <li>• Helps treat and prevent diaper rash.</li> <li>• Temporarily protects minor cuts • scrapes • burns</li> <li>• Dries the oozing and weeping of • poison ivy • poison oak • poison sumac</li> </ul>
<p><b>Warnings • For External Use Only.</b></p>
<p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>• do not get into eyes</li> </ul>
<p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>• condition worsens</li> <li>• symptoms last more than 7 days or clear up and occur again in a few days.</li> </ul>
<p><b>Keep out of reach of children</b></p> <ul style="list-style-type: none"> <li>• if swallowed, get medical help or contact a Poison Control Center right away</li> </ul>
<p><b>Directions:</b></p> <ul style="list-style-type: none"> <li>• Apply liberally as needed</li> <li>• For diaper rash • change wet and soiled diapers promptly • allow to dry</li> <li>• apply ointment liberally with each diaper change</li> </ul>
<p><b>Other information:</b></p> <ul style="list-style-type: none"> <li>• store at room temperature 15° - 30°C (59° - 86°F)</li> <li>• avoid excessive heat</li> <li>• contains color additives including FD&amp;C Yellow No. 5 (tartrazine).</li> </ul>
<p><b>Inactive ingredients</b> Aloe Barbadosensis Leaf Juice, Cetyl Alcohol, Cholecalciferol, Diazolidinyl Urea, Fragrance, Lanolin, Methylparaben, Mineral Oil, Petrolatum, Purified Water, Retinyl Palmitate, Sodium Borate, Stearic Acid, Tocopheryl Acetate, Yellow 5, Yellow 6, Zea Mays (Corn) Oil</p>
<p>Manufactured for: <b>NDC #67777-226-02</b> Dynarex Corporation Orangeburg, NY 10962 Made in Israel www.dynarex.com</p>
 <p>1194IN.Rev2</p>

## Zinc Oxide Ointment

### ZINC OXIDE

zinc oxide ointment

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68786-226
<b>Route of Administration</b>	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: 059QF0K00R)	
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