# DYNA1195- zinc oxide ointment Blossom Pharmaceuticals

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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#### **Dyna1195 Ointment**

Active Ingredient Purpose

Zinc Oxide (1.8% w/w) Skin Protectant

#### Purpose:

- 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.

#### Dosage and Administration:

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 (Tartrazine)

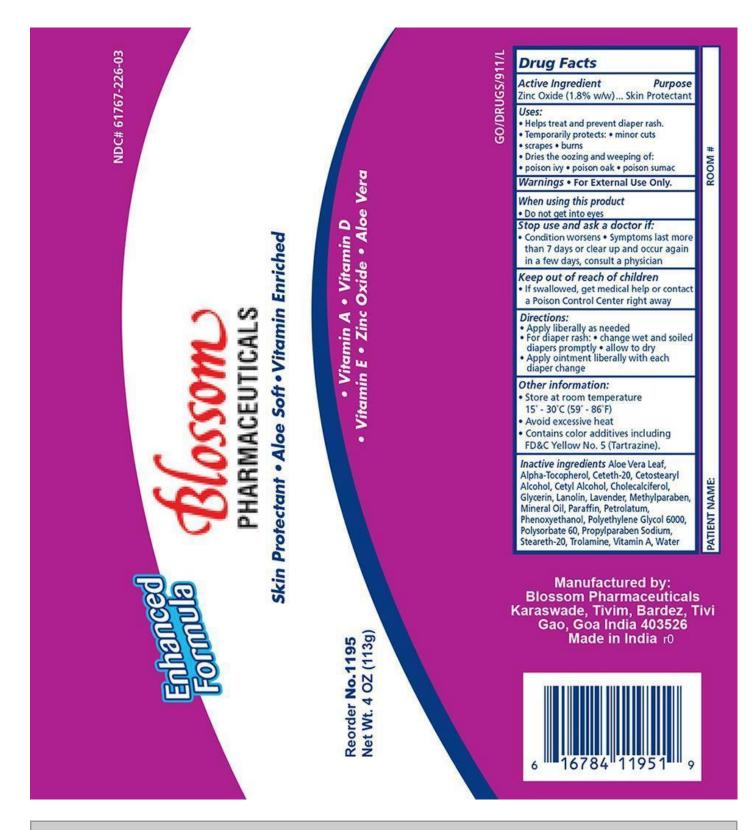
Indications: For use as a general skin protectant and diaper rash.

Inactive ingredients:

Aloe Vera Leaf, Alpha-Tocopherol, Ceteth-20, Cetostearyl Alcohol, Cetyl Alcohol, Cholecalciferol, Glycerin, Lanolin, Lavender perfume, Methylparaben, Mineral Oil, Petrolatum, Propylparaben, Trolamine, Vitamin A, Water

### **Principal Display Panel**

Dyna1195 Skin Protectant Dyna1195.jpg



#### **DYNA1195**

zinc oxide ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61767-226
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	
LANOLIN (UNII: 7EV65EAW6H)		
<b>CETETH-20</b> (UNII: 1835H2IHHX)		
MINERAL OIL (UNII: T5L8T28FGP)		
METHYLPARABEN (UNII: A218 C7HI9 T)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
GLYCERIN (UNII: PDC6A3C0OX)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
CHOLECALCIFEROL (UNII: 1C6 V77QF41)		
VITAMIN A (UNII: 81G40H8B0T)		
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
PETROLATUM (UNII: 4T6H12BN9U)		
TROLAMINE (UNII: 903K93S3TK)		
WATER (UNII: 059QF0KO0R)		

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:61767-226-01	5 g in 1 PACKET				
2	NDC:61767-226-02	15 g in 1 PACKET				
3	NDC:61767-226-03	114 g in 1 TUBE				
4	NDC:61767-226-04	427.5 g in 1 JAR				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	10/23/2014		

## **Labeler** - Blossom Pharmaceuticals (677381470)

Revised: 10/2014 Blossom Pharmaceuticals