

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.

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

NDC# 61767-226-03

Enhanced Formula

Blossom

PHARMACEUTICALS

Skin Protectant • Aloe Soft • Vitamin Enriched

Reorder No. 1195
Net Wt. 4 OZ (113g)

- Vitamin A • Vitamin D
- Vitamin E • Zinc Oxide • Aloe Vera

GO/DRUGS/911/L

Drug Facts

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

Uses:

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

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Stop use and ask a doctor if:

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Keep out of reach of children

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

Directions:

- 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 15° - 30°C (59° - 86° F)
- Avoid excessive heat
- Contains color additives including FD&C Yellow No. 5 (Tartrazine).

Inactive ingredients Aloe Vera Leaf, Alpha-Tocopherol, Ceteth-20, Cetostearyl Alcohol, Cetyl Alcohol, Cholecalciferol, Glycerin, Lanolin, Lavender, Methylparaben, Mineral Oil, Paraffin, Petrolatum, Phenoxyethanol, Polyethylene Glycol 6000, Polysorbate 60, Propylparaben Sodium, Steareth-20, Trolamine, Vitamin A, Water

ROOM #

PATIENT NAME:

Manufactured by:
Blossom Pharmaceuticals
Karaswade, Tivim, Bardez, Tivi
Gao, Goa India 403526
Made in India r0



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)	
CETETH-20 (UNII: I835H2IHHX)	
MINERAL OIL (UNII: T5L8T28FGP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
VITAMIN A (UNII: 81G40H8B0T)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PETROLATUM (UNII: 4T6H12BN9U)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

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