

DYNA1199 WITH DIMETHICONE- 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.

Dyna1199 with Dimethicone Ointment

Active Ingredient	Purpose
Zinc Oxide 2%	Diaper Rash
Dimethicone 1.8%	Skin Protectant

Purpose:

- Helps treat and prevent diaper rash
- 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
- over large areas of the body
- if you are allergic to any of these ingredients

Keep out of reach of children.

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

Dosage and Administration:

For poison ivy, oak and sumac:

- Apply ointment liberally as often as needed

For diaper Rash:

- change wet and soiled diapers promptly
- clean the diaper area and allow to dry
- apply ointment liberally with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged.

Other information:

- Do not use if seal is punctured or not visible
- Store at room temperature 15⁰ - 30⁰ °C (59⁰ - 86⁰ °F)
- 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

DynaShield Skin Protectant

DynaDi1199.jpg

NDC# 61767-228-01

**Enhanced
Formula**

Blossom
PHARMACEUTICALS

**Skin Protectant Barrier Cream
with Dimethicone**

Reorder No.1199
Net Wt. 4 OZ (113g)

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

GO/DRUGS/911/L

Drug Facts	
Active Ingredient (in each gram)	Purpose
Zinc Oxide (200 mg)	Diaper Rash
Dimethicone 1.8%	Skin Protectant
Uses:	
<ul style="list-style-type: none"> Helps treat and prevent diaper rash. Dries the oozing and weeping of poison ivy • poison oak • poison sumac 	
Warnings • For External Use Only.	
When using this product	
<ul style="list-style-type: none"> do not get into eyes 	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> condition worsens symptoms last more than 7 days or clear up and occur again in a few days, consult a physician over large areas of the body if you are allergic to any of these ingredients 	
Keep out of reach of children	
<ul style="list-style-type: none"> if swallowed, get medical help or contact a Poison Control Center right away 	
Directions: For diaper rash	
<ul style="list-style-type: none"> change wet and soiled diapers promptly cleanse the diaper area and allow to dry Apply ointment liberally with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged 	
<i>For poison ivy, oak and sumac</i>	
<ul style="list-style-type: none"> apply ointment liberally as often as needed 	
Other information:	
<ul style="list-style-type: none"> Do not use if seal is punctured or not visible Store at room temperature 15° - 30°C (59° - 86°F) Avoid excessive heat 	
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



DYNA1199 WITH DIMETHICONE

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61767-228
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: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	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:61767-228-01	5 g in 1 PACKET		
2	NDC:61767-228-02	15 g in 1 PACKET		
3	NDC:61767-228-03	114 g in 1 TUBE		
4	NDC:61767-228-04	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