

TRIPLE MEDICATED FOR DIAPER RASH- zinc oxide paste
Summers Laboratories Inc

SUMMERS LABS (as PLD) - TRIPLE PASTE (11086-021)

ACTIVE INGREDIENT

ZINC OXIDE 12.8%

PURPOSE

SKIN PROTECTANT

USES

- HELPS TREAT AND PREVENT DIAPER RASH
- PROTECTS CHAFED SKIN DUE TO DIAPER RASH AND HELPS PROTECT FROM WETNESS

WARNINGS

FOR EXTERNAL USE ONLY

When using this product

- DO NOT GET INTO EYES

Stop and ask a doctor if

- condition worsens or does not improve within 7 days

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

- Change wet and soiled diapers promptly
- Cleanse the diaper area and allow skin to dry
- Apply ointment liberally as often as necessary, with each diaper change, especially at bedtime or any time exposure to wet diapers may be prolonged

INACTIVE INGREDIENTS

white petrolatum, corn starch, anhydrous lanolin, stearyl alcohol, beeswax, bisabolol, cholesterol, water, glycerine, oat (avena sativa) kernel extract, polysorbate 80.

TRIPLE MEDICATED FOR DIAPER RASH

zinc oxide paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11086-021
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	12.8 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
STARCH, CORN (UNII: O8232NY3SJ)	
LANOLIN (UNII: 7EV65EAW6H)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
YELLOW WAX (UNII: 2ZA36H0S2V)	8 g in 100 g
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C00X)	
OAT (UNII: Z6J799EAJK)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11086-021-01	56.7 g in 1 TUBE; Type 0: Not a Combination Product	10/30/2013	
2	NDC:11086-021-02	454 g in 1 JAR; Type 0: Not a Combination Product	10/30/2013	
3	NDC:11086-021-03	240 g in 1 PACKAGE; Type 0: Not a Combination Product	10/30/2013	
4	NDC:11086-021-05	284 g in 1 PACKAGE; Type 0: Not a Combination Product	10/30/2013	
5	NDC:11086-021-06	100 g in 1 PACKAGE; Type 0: Not a Combination Product	10/30/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	10/30/2013	

Labeler - Summers Laboratories Inc (002382612)

Revised: 10/2023

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Inc