

ZINCTRAL- zinc oxide paste
PureTek Corporation

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.

Zinctral
Zinc Oxide 20% (3% as Calamine)

Active ingredient

Zinc Oxide 20.0%
(3.0% as Calamine)

Purpose

Skin Protectant

Uses

- dries the oozing and weeping of poison:
- ivy
- oak
- sumac
- Helps treat and prevent diaper rash. Protects minor skin irritations due to diaper rash and helps protect from wetness.

Warnings

For external use only

When using this product

- do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

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

Directions

- Cleanse skin with DiaSinc All Purpose Cleansing Spray and apply paste to area as needed.
- Change wet and soiled diapers promptly, cleanse the diaper area, and allow to dry.

Apply product liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged.

Other information

- protect from freezing
- avoid excessive heat
- Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Inactive ingredients:

Aleurites Moluccana (Kukui) Seed Oil, Aloe Barbadensis (Aloe Vera) Leaf Juice Powder, Carthamus Tinctorius (Safflower) Seed Oil, Fragrance (Contains: Alpha-Isomethyl Ionone, Butylphenyl Methylpropional, Coumarin, Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde, Limonene, Linalool), GenRx Complex® [Consisting of: Bisabolol, Calcium Pantothenate (Vitamin B5), Carthamus Tinctorius (Safflower) Oleosomes, Maltodextrin, Niacinamide (Vitamin B3), Pyridoxine HCl (Vitamin B6), Silica, Sodium Ascorbyl Phosphate (Vitamin C), Sodium Hyaluronate, Sodium Starch Octenylsuccinate, DL-Alpha-Tocopheryl Acetate (Vitamin E), Zingiber Officinale (Ginger) Root Extract], Petrolatum, Phenoxyethanol, Zea Mays (Corn) Starch.

Zinctral™

Manufactured in the USA by:

PureTek Corporation

Panorama City, CA 91402

For questions or information call toll-free: 877-921-7873

NDC 59088-627-05

Zinctral™

DERMACINRx

Soothes and protects against diaper rash and bedsores

Use under the direction of a medical practitioner

Skin Protectant Paste 2 oz. (57 g)

Rev. 38523-01

Drug Facts

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Zinc Oxide 20% (3% as Calamine)	Skin Protectant

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List No. 627051AA
Rev. 38524-01



Please Recycle

ZINCTRAL

zinc oxide paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59088-627
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
LEVOMENOL (UNII: 24WE03BX2T)	
KUKUI NUT OIL (UNII: TP11QR7B8R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CALCIUM PANTOTHENATE (UNII: 568ET80C3D)	
CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PETROLATUM (UNII: 4T6H12BN9U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
GINGER (UNII: C5529G5JPQ)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
SAFFLOWER OIL (UNII: 65UEH262IS)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-627-05	57 g in 1 TUBE; Type 0: Not a Combination Product	03/24/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/24/2023	

Labeler - PureTek Corporation (785961046)