

SHIELD AND PROTECT BARRIER CREAM- petroleum, zinc oxide cream gentell inc

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.

Shield and Protect Barrier Cream

Active Ingredients

Zinc Oxide

Petrolatum

Keep out of reach of children

Keep out of reach of Children

Inactive Ingredients

Purified water

Mineral oil

Sodium Chloride

Castor wax

Bees wax

Imidazolidinyl Urea

Propylparaben

Methylparaben

Vitamin A Palmitate

Cetostearyl alcohol

Vitamin D₃

Purpose

Gentell Shield & Protect Moisture Barrier Cream forms a water-shedding shield that helps soothe and protect dry or irritated skin. Therapeutic against irritation from urine, feces, and other bodily secretions. Shield & Protect leaves skin soft and smooth rather than irritated and greasy. Ideal for sensitive skin.

Warnings

For external use only

Avoid eye contact

Discontinue use and contact a physician if condition worsens, or symptoms persist from more than seven days

Keep this out of the reach of children

Dosage & Administration

Carefully cleanse the area and pat dry thoroughly. Apply liberally to desired areas as often as necessary or when prolonged exposure is anticipated.

Indication and usage

Shield & Protect Moisture Barrier Cream helps restore, replenish and soothe dry irritated or otherwise compromised skin.

It helps treat or prevent minor skin irritations associated with incontinence.

Protects from and seals out wetness

Primary Label



Shield & Protect[®]

Moisture Barrier Cream

Shields skin from wetness with Zinc Oxide

Protects skin with a Dimethicone barrier

Nourishes skin with
Vitamins A&D



REGULAR

GEN-23140

Net Weight 4 oz. • 115 g

SHIELD AND PROTECT BARRIER CREAM

petroleum, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61554-500
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4.13 g in 100 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	10.32 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
LIGHT MINERAL OIL (UNII: N6K5787QVP)	20.64 g in 100 g
CHOLECALCIFEROL (UNII: 1C6V77QF41)	0.05 g in 100 g
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	0.03 g in 100 g
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.48 g in 100 g
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	0.36 g in 100 g
WATER (UNII: 059QF0KO0R)	59.52 g in 100 g
PROPYLPARABEN (UNII: Z8IX2SC1OH)	0.1 g in 100 g
IMIDUREA (UNII: M629807ATL)	0.3 g in 100 g
METHYLPARABEN (UNII: A2I8C7HI9T)	0.25 g in 100 g
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	3.44 g in 100 g
SYNTHETIC BEESWAX (UNII: 08MNR5YE2R)	0.36 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61554-500-01	118 g in 1 TUBE; Type 0: Not a Combination Product	11/13/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	11/13/2014	

Labeler - gentell inc (170967876)

Establishment

Name	Address	ID/FEI	Business Operations
gentell inc		170967876	manufacture(61554-500)

Revised: 5/2021

gentell inc