

SHIELD AND PROTECT BARRIER CREAM- petroleum, zinc oxide cream Gentell LLC

Shield and Protect Moisture Barrier Ointment

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

Hydrogenated Castor Wax

Beeswax

Imidazolidinyl Urea

Paraffin

Propylparaben

Methylparaben

Vitamin A Palmitate

Cetostearyl alcohol

Vitamin D

Vitamin E(alpha tocopherol)

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 very irritated or otherwise compromised skin.

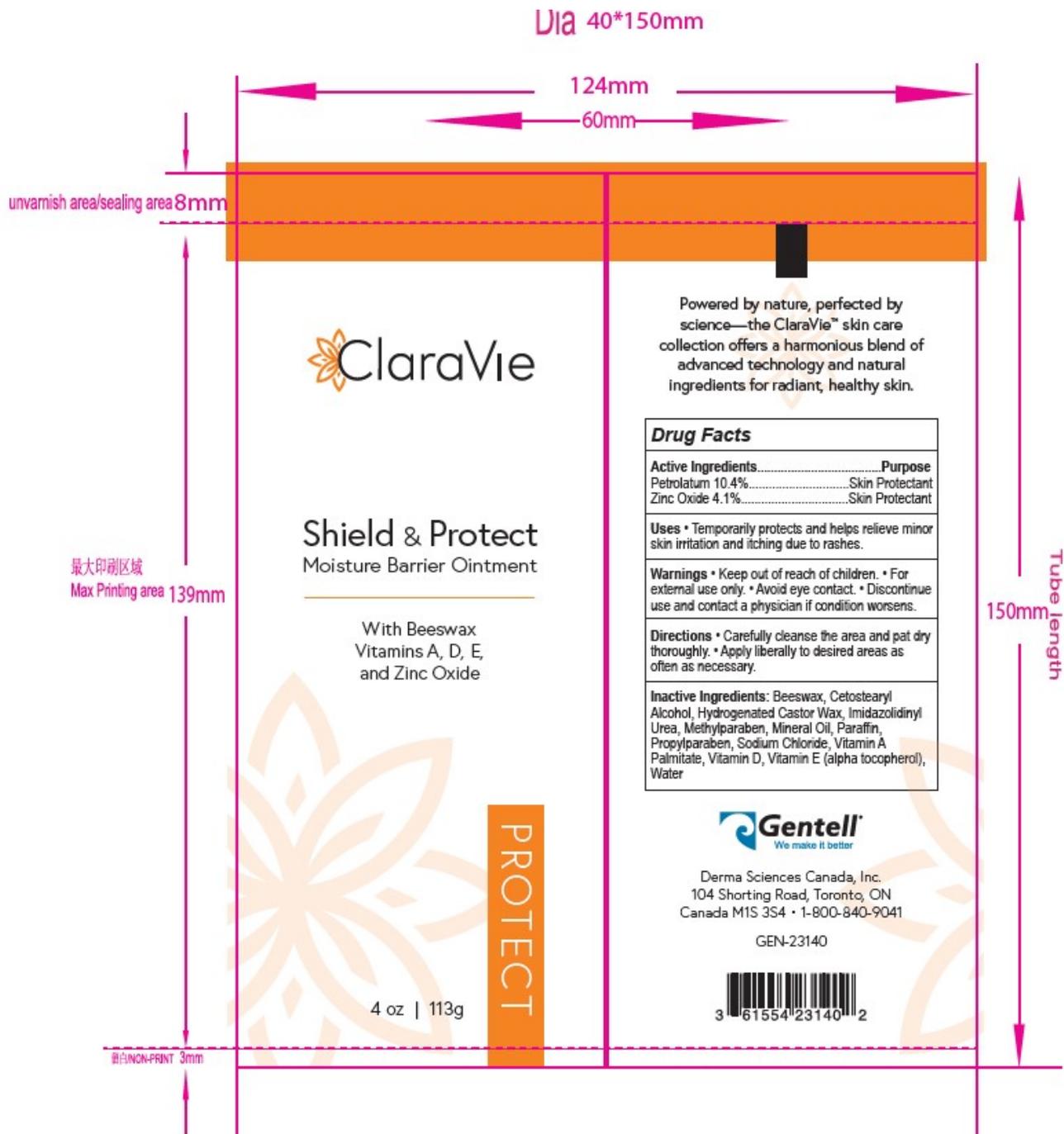
It helps treat or prevent minor skin irritations associated with incontinence.

Protects from and seals out wetness

Primary Label

4oz

Shield and Protect



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
PARAFFIN (UNII: I9O0E3H2ZE)	
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
LIGHT MINERAL OIL (UNII: N6K5787QVP)	20.64 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 Drug	M016	11/13/2014	

Labeler - Gentell LLC (170967876)

Establishment

Name	Address	ID/FEI	Business Operations
Gentell LLC		170967876	manufacture(61554-500)

Revised: 10/2024

Gentell LLC