

SUPER MAX BARRIER CREAM- white 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.

Super Max Barrier Cream

Warnings and precautions

Keep out of reach of children

Purpose

Gentell SuperMax Moisture Barrier Cream protects healthy and intact skin from breaking down during compromised skin conditions.

Active Ingredient

Petrolatum

Zinc Oxide

Dosage & administration

Clean the affected area, and dry thoroughly. Apply SuperMax liberally and as often as necessary, especially when prolonged exposure to moisture is anticipated.

Warnings

For external use only

Avoid all contact with eyes

If condition fails to improve after seven days, consult a physician

Keep out of reach of children

If swallowed, seek medical attention or call a Poison Control Center immediately

inactive ingredients

Mineral Oil

Castor oil

DMDM Hydantoin

Aloe Vera

Vitamin A Palmitate

vitamin D


Peruvian Balsam

Indication & Usage

Gentell SuperMax Moisture Barrier Cream protects healthy and intact skin from breaking down during compromised skin conditions

Principal Label





**Maximum strength
incontinence protection**

Will not clog pores of diapers

**Cleans off as easily
as it goes on**

GEN-23340

Net Weight 4 oz • 118 ml

SUPER MAX BARRIER CREAM

white petroleum, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61554-700
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	16 g in 100 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	50 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
LIGHT MINERAL OIL (UNII: N6K5787QVP)	16 g in 100 g
CASTOR OIL (UNII: D5340Y2I9G)	16 g in 100 g
DMDM HYDANTOIN (UNII: BYR0546TOW)	0.2 g in 100 g
ALOE VERA LEAF POLYSACCHARIDES (UNII: W21O437517)	0.1 g in 100 g
CHOLECALCIFEROL (UNII: 1C6V77QF41)	0.4 g in 100 g
BALSAM PERU (UNII: 8P5F881OCY)	1 g in 100 g
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	0.3 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61554-700-01	113.4 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	part346	11/13/2014	

Labeler - gentell inc (170967876)

Establishment

Name	Address	ID/FEI	Business Operations
gentell inc		170967876	manufacture(61554-700)