GENRX SKIN BARRIER- dimethicone cream
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.

Active ingredient

Dimethicone 1.5%

Purpose

Skin Protectant

Uses

■ for the treatment and/or prevention of diaper rash
■ temporarily protects and helps relieve chapped or cracked skin

Warnings

For external use only

Do not use on

■ deep or puncture wounds ■ animal bites ■ serious burns

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

■ apply liberally as needed

Other information

■ protect from freezing ■ avoid excessive heat

Inactive ingredients

Aleurites moluccana seed oil, *Aloe barbadensis* (*Aloe vera*) leaf juice, C12-13 pareth-23, C12-13 pareth-3, *Carthamus tinctorius* (safflower) seed oil, cetyl dimethicone, cyclopentasiloxane, dicaprylyl carbonate, dimethiconol, divinyldimethicone/dimethicone copolymer, fragrance, GenRx Complex™ [consisting of: bisabolol, calcium pantothenate (vitamin B_5), *Carthamus tinctorius* (safflower) oleosomes, maltodextrin, niacinamide (vitamin B_3), pyridoxine HCl (vitamin B_6), silica, sodium ascorbyl

phosphate (vitamin C), sodium starch octenylsuccinate, tocopheryl acetate (vitamin E), *Zingiber officinale* (ginger) root extract], PEG/PPG-18/18 dimethicone, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, phenoxyethanol, propylene glycol, propylheptyl caprylate, purified water, sodium chloride, sodium hyaluronate.

Skin Barrier Cream with GenRx Complex™ (4 oz tube label)

Room No.

Name

Drug Facts

Active ingredient — **Purpose**
Dimethicone 1.5% ..... Skin Protectant

Uses
- for the treatment and/or prevention of diaper rash
- temporarily protects and helps relieve chapped or cracked skin

Warnings
For external use only

Do not use on ■ deep or puncture wounds ■ animal bites ■ serious burns

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
- apply liberally as needed

Other information
- protect from freezing
- avoid excessive heat

Inactive ingredients *Aleurites moluccana* seed oil, *Aloe barbadensis* (*Aloe vera*) leaf juice, C12-13 pareth-23, C12-13 pareth-3, *Carthamus tinctorius* (safflower) seed oil, cetyl dimethicone, cyclopentasiloxane, dicaprylyl carbonate, dimethiconol, divinyldimethicone/dimethicone copolymer, fragrance, GenRx Complex™ [consisting of: bisabolol, calcium pantothenate (vitamin B_5), *Carthamus tinctorius* (safflower) oleosomes, maltodextrin, niacinamide (vitamin B_3), pyridoxine HCl (vitamin B_6), silica, sodium ascorbyl phosphate (vitamin C), sodium starch octenylsuccinate, tocopheryl acetate (vitamin E), *Zingiber officinale* (ginger) root extract], PEG/PPG-18/18 dimethicone, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, phenoxyethanol, propylene glycol, propylheptyl caprylate, purified water, sodium chloride, sodium hyaluronate.

7 31477 50001 3

LATEX-FREE

PureTek Guarantee: Every PureTek product is manufactured and tested to meet or exceed all USP standards.

Manufactured in the USA by:
PureTek Corporation, San Fernando, CA 91340 • 877-921-7873
For more info, visit: www.genrxwoundcare.com
LIST NO. 85108 AAA Rev: 240273-00

NDC 59088-851-08

Gen+Rx™

WOUND CARE
Hypo-Allergenic

Skin Barrier Cream
with
GenRx Complex™

Protects, nourishes and moisturizes advanced dry, cracked skin
Provides long-lasting hydration
Helps protect against bedsores, when used as part of an overall treatment

- Physician Tested
- Non-sensitizing
- Promotes Healing
- Clinically Proven
- Helps Skin Cell Renewal
- Paraben Free

4 fl oz / 118 mL

GENRX SKIN BARRIER
dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59088-851
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dimethicone (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	15 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
KUKUI NUT OIL (UNII: TP11QR7B8R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
C12-13 PARETH-23 (UNII: J1WW1510L4)	
C12-13 PARETH-3 (UNII: DMC6N3419L)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
DIMETHICONOL (40 CST) (UNII: 343C7U75XW)	
LEVOMENOL (UNII: 24WE03BX2T)	
CALCIUM PANTOTHENATE (UNII: 568ET80C3D)	
CARTHAMUS TINCTORIUS SEED OLEOSOMES (UNII: 9S60Q72309)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
GINGER (UNII: C5529G5JPQ)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLHEPTYL CAPRYLATE (UNII: 991Z19V2OD)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-851-69	144 in 1 CARTON		
1	NDC:59088-851-01	4 mL in 1 POUCH		
2	NDC:59088-851-05	59 mL in 1 TUBE		
3	NDC:59088-851-08	118 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/08/2013	

Labeler - PureTek Corporation (785961046)

Establishment

Name	Address	ID/FEI	Business Operations
PureTek Corporation		785961046	manufacture(59088-851) , pack(59088-851) , label(59088-851)

Revised: 1/2013 PureTek Corporation