# GENRX DAILY DEFENSE SKIN REPAIRING- 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.

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#### **Active ingredient**

Dimethicone 1.75%

#### **Purpose**

Skin Protectant

#### Uses

■ 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 cream liberally as needed

#### Other information

■ protect from freezing ■ avoid excessive heat

#### **Inactive ingredients**

Aleurites moluccana seed oil, Aloe barbadensis (Aloe vera) leaf juice, butylene glycol, Carthamus tinctorius (safflower) seed oil, cetyl alcohol, dimethicone crosspolymer, disodium EDTA, fragrance, glycerin, glyceryl stearate, GenRx Complex<sup>TM</sup> [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-100 stearate,

pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, phenoxyethanol, purified water, sodium hyaluronate, stearic acid, triethanolamine.

### Daily Defense Skin Repairing Cream with GenRx Complex<sup>0</sup>TM (4 fl. oz tube label)

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



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Manufactured in the USA by: PureTek Corporation, San Fernando, CA 91340 • 877-921-7873 For more info, visit: www.genrxwoundcare.com

> LIST NO. 82908 AAA Rev: 240277-00

NDC 59088-829-08



### WOUND CARE Hypo-Allergenic



## **Daily Defense Skin Repairing Cream**

with GenRx Complex™

**Restores and hydrates** dry, cracked skin 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 DAILY DEFENSE SKIN REPAIRING

dimethicone cream

#### **Product Information**

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:59088-829
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Dimethicone (Dimethicone)	Dimethicone	17.5 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
KUKUI NUT OIL		
ALOE VERA LEAF		
BUTYLENE GLYCOL		
SAFFLOWER OIL		
CETYL ALCOHOL		
DIMETHICO NE/DIENE DIMETHICO NE CROSSPOLYMER		
EDETATE DISO DIUM		
GLYCERIN		
GLYCERYL MONOSTEARATE		
LEVOMENOL		
CALCIUM PANTO THENATE		
CARTHAMUS TINCTORIUS SEED OLEOSOMES		
MALTO DEXTRIN		
NIACINAMIDE		
PYRIDO XINE HYDRO CHLO RIDE		
SILICON DIO XIDE		
SODIUM ASCORBYL PHOSPHATE		
.ALPHATO COPHEROL ACETATE, DL-		
GINGER		
PEG-100 STEARATE		
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDRO XYPHENYL)PRO PIO NATE)		
PHENOXYETHANOL		
WATER		
HYALURO NATE SO DIUM		
STEARIC ACID		
TROLAMINE		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-829-69	144 in 1 CARTON		
1	NDC:59088-829-01	4 mL in 1 POUCH		
2	NDC:59088-829-05	59 mL in 1 TUBE		
3	NDC:59088-829-08	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(59088-829), pack(59088-829), label(59088-829)

Revised: 1/2013 PureTek Corporation