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.

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

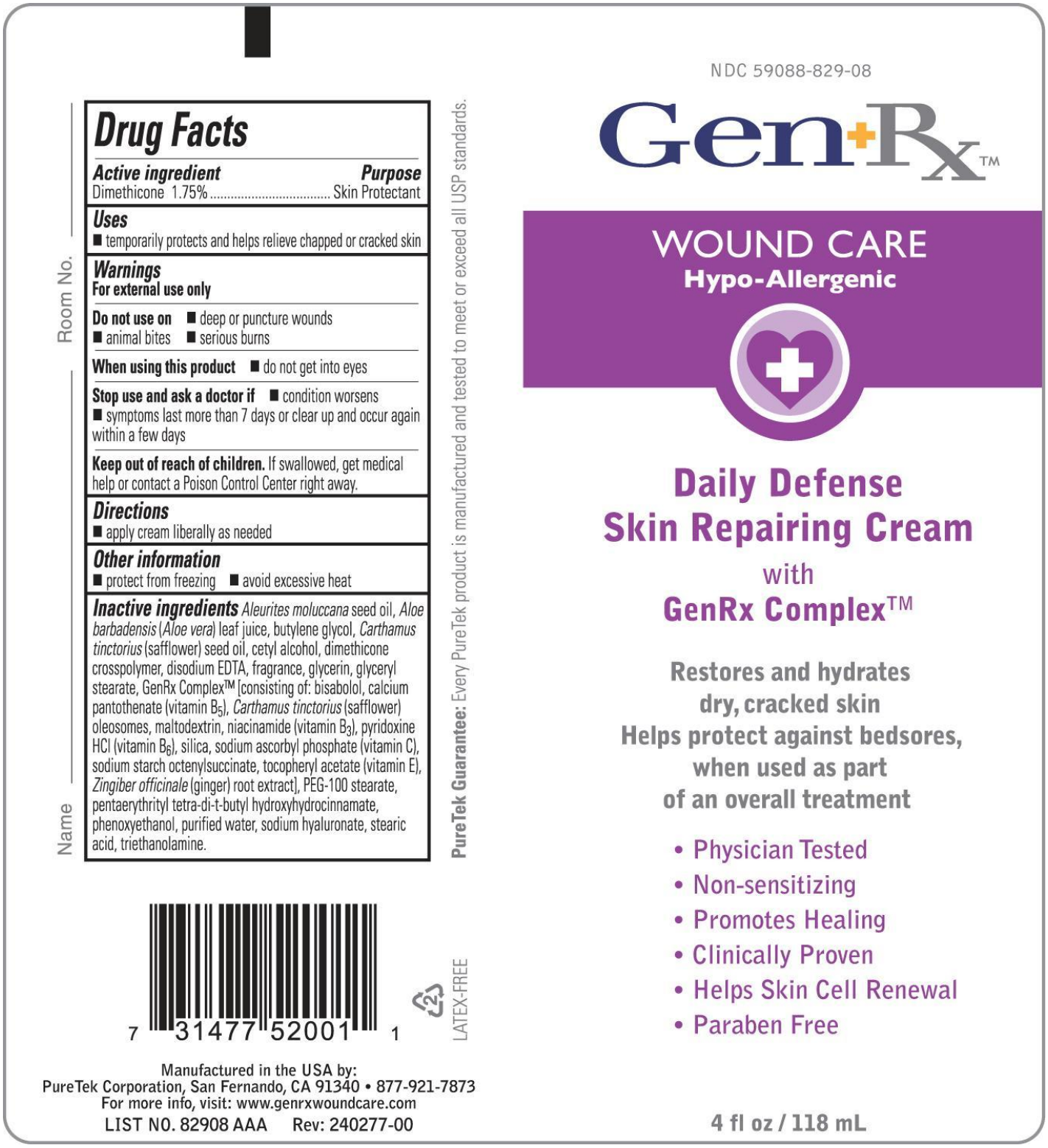
■ protect from freezing ■ avoid excessive heat

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™ [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™ (4 fl. oz tube label)



GENRX DAILY DEFENSE SKIN REPAIRING

dimethicone cream

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dimethicone (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	17.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
KUKUI NUT OIL (UNII: TP11QR7B8R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE/DIENE DIMETHICONE CROSSPOLYMER (UNII: RSA9I561OK)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
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-100 STEARATE (UNII: YD01N1999R)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	

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