

**GENRX ALL PURPOSE CLEANSING- dimethicone lotion**  
**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
- cleanses, moisturizes, nourishes, and protects skin
- it can be used on face, body and perineal area

**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 recur 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 cleanser to damp cloth or to skin/perineal area
- gently wipe clean (no rinsing necessary)
- apply as needed
- apply GenRx protectant cream or paste as necessary

**Other information**

- protect from freezing
- avoid excessive heat

**Inactive ingredients**

*Aleurites moluccana* seed oil, *Aloe barbadensis* (*Aloe vera*) leaf juice, butylene glycol, caprylyl glycol,

cetyl alcohol, chlorphenesin, disodium EDTA, fragrance, glycerin, *Glycine soja* (soybean) oil, glyceryl stearate, GenRx Complex™ [consisting of: bisabolol, calcium pantothenate (vitamin B<sub>5</sub>), *Carthamus tinctorius* (safflower) oleosomes, maltodextrin, niacinamide (vitamin B<sub>3</sub>), pyridoxine HCl (vitamin B<sub>6</sub>), silica, sodium ascorbyl phosphate (vitamin C), sodium starch octenylsuccinate, tocopheryl acetate (vitamin E), *Zingiber officinale* (ginger) root extract], linoleamidopropyl PG-dimonium chloride phosphate, PEG-100 stearate, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, phenoxyethanol, purified water, sodium hyaluronate, stearic acid, triethanolamine.

## All Purpose Cleansing Lotion with GenRx Complex™ (8 oz bottle label)

Room No. \_\_\_\_\_  
Name \_\_\_\_\_

Drug Facts	
<b>Active ingredient</b> Dimethicone 1.75%	<b>Purpose</b> Skin Protectant
<b>Uses</b> <ul style="list-style-type: none"> <li>■ temporarily protects and helps relieve chapped or cracked skin</li> <li>■ cleanses, moisturizes, nourishes, and protects skin</li> <li>■ it can be used on face, body and perineal area</li> </ul>	
<b>Warnings</b> For external use only	
<b>Do not use on</b> <ul style="list-style-type: none"> <li>■ deep or puncture wounds</li> <li>■ animal bites</li> <li>■ serious burns</li> </ul>	
<b>When using this product</b> <ul style="list-style-type: none"> <li>■ do not get into eyes</li> </ul>	
<b>Stop use and ask a doctor if</b> <ul style="list-style-type: none"> <li>■ condition worsens</li> <li>■ symptoms last more than 7 days or clear up and recur within a few days</li> </ul>	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> <ul style="list-style-type: none"> <li>■ apply cleanser to damp cloth or to skin/perineal area</li> <li>■ gently wipe clean (no rinsing necessary)</li> <li>■ apply as needed</li> <li>■ apply GenRx protectant cream or paste as necessary</li> </ul>	
<b>Other information</b> <ul style="list-style-type: none"> <li>■ protect from freezing</li> <li>■ avoid excessive heat</li> </ul>	
<b>Inactive ingredients</b> <i>Aleurites moluccana</i> seed oil, <i>Aloe barbadensis</i> (Aloe vera) leaf juice, butylene glycol, caprylyl glycol, cetyl alcohol, chlorphenesin, disodium EDTA, fragrance, glycerin, <i>Glycine soja</i> (soybean) oil, glyceryl stearate, GenRx Complex™ [consisting of: bisabolol, calcium pantothenate (vitamin B <sub>5</sub> ), <i>Carthamus tinctorius</i> (safflower) oleosomes, maltodextrin, niacinamide (vitamin B <sub>3</sub> ), pyridoxine HCl (vitamin B <sub>6</sub> ), silica, sodium ascorbyl phosphate (vitamin C), sodium starch octenylsuccinate, tocopheryl acetate (vitamin E), <i>Zingiber officinale</i> (ginger) root extract], linoleamidopropyl PG-dimonium chloride phosphate, PEG-100 stearate, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, phenoxyethanol, purified water, sodium hyaluronate, stearic acid, triethanolamine.	

Manufactured in the USA by:  
PureTek Corporation, San Fernando, CA 91340 • 877-921-7873  
For more info, visit: [www.genrxwoundcare.com](http://www.genrxwoundcare.com)  
LIST NO. 64416 AAA Rev: 240268-00

NDC 59088-644-16

WOUND CARE  
Hypo-Allergenic

All Purpose Cleansing Lotion  
with  
GenRx Complex™

Cleanses, nourishes, moisturizes, hydrates  
and provides protective moisture barrier

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

8 fl oz / 237 mL

LATEX-FREE

7 31477 48001 8

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

## GENRX ALL PURPOSE CLEANSING

dimethicone lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59088-644
<b>Route of Administration</b>	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)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
SOYBEAN OIL (UNII: 241ATL177A)	
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: 836SJK51DR)
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)
GINGER (UNII: C5529G5JPK)
LINOLEAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: 5Q87K461JO)
PEG-100 STEARATE (UNII: YD01N1999R)
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
WATER (UNII: 059QF0K00R)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
STEARIC ACID (UNII: 4ELV7Z65AP)
TROLAMINE (UNII: 9O3K93S3TK)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-644-16	237 mL in 1 BOTTLE, PLASTIC		

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(59088-644) , pack(59088-644) , label(59088-644)