SCAR GEL ADVANCED FORMULA- allantoin cream Natureplex LLC

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.

Scar Gel Advanced Formula

Drug Facts

Active ingredient

Allantoin 0.5%

Purpose

Skin Protectant

Use

Temporarily protects minor:

- cuts
- scrapes
- burns

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

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away: 800-222-1222.

Directions

apply as needed

Other information

- store at 15 to 30°C (59 to 86°F)
- **Tamper Evident:** DO NOT USE IF SEAL ON TUBE IS PUNCTURED OR MISSING.

Inactive ingredients

alcohol denatured, *allium cepa* (onion) bulb extract, carbomer, fragrance, hydrolized collagen, methylparaben, panthenol, PEG-8, purified water, sodium hyaluronate, sodium hydroxide, sorbic acid

Questions or comments?

1-866-323-0107 or visit www.natureplex.com

PRINCIPAL DISPLAY PANEL - 35 g Tube Box

ADVANCED FORMULA

 $Natureplex^{TM}$

ScarGel

With

Allantoin

Specially Formulated For Scars

Helps Soften & Smooth

The Appearance Of Scars

NET WT. 1.25 Oz.(35g)



allantoin cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67234-027
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALLANTO IN (UNII: 344S277G0Z) (ALLANTO IN - UNII:344S277G0Z)	ALLANTOIN	0.005 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)		
COLLAGEN ALPHA-1(III) (HUMAN) (UNII: 5D8UAE62VB)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
ONION (UNII: 492225Q21H)		
PANTHENOL (UNII: WV9CM0O67Z)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
WATER (UNII: 059QF0KO0R)		
ALCOHOL (UNII: 3K9958V90M)		
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)		
SODIUM HYDROXIDE (UNII: 55X04QC32I)		
SORBIC ACID (UNII: X045WJ989B)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:67234-027-01	1 in 1 BOX	11/0 1/20 13	
1	35 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	11/0 1/20 13	

Labeler - Natureplex LLC (062808196)

Establishment			
Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(67234-027)

Revised: 5/2018 Natureplex LLC