SCARDERM- allantoin gel
Sinsin Pharmaceutical Co., Ltd.

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.

Scarderm

Drug Facts

Active Ingredient

Allantoin 1%

Purpose

Skin Protectant

Use

Temporatrily protects and helps relieve chapped or cracked skin

Warnings

For external use only

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

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

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

Directions

Apply as needed.

Other information

Store at room temperature

Inactive Ingredients

Water (purified), Allium Cepa (Onion) Bulb Extract, Heparin Sodium, Polyethylene Glycol, Concentrated Glycerin, Butylene Glycol, Sorbic Acid, Methylparaben, Jantangeom, Carbomer 940, Triethanolamine

Questions or Comments?

For more information call 714-266-0391

PRINCIPAL DISPLAY PANEL - 20 g Tube Box

SCARDERM

allantoin gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55264-050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Allantoin (UNII: 344S277G0Z) (Allantoin - UNII:344S277G0Z)	Allantoin	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Onion (UNII: 492225Q21H)	
Heparin Sodium (UNII: ZZ45AB24CA)	
Polyethylene Glycol 400 (UNII: B697894SGQ)	
Glycerin (UNII: PDC6A3C0OX)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Sorbic Acid (UNII: X045WJ989B)	
Methylparaben (UNII: A2I8C7HI9T)	
Xanthan Gum (UNII: TTV12P4NEE)	
Panthenol (UNII: WV9CM0O67Z)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
Trolamine (UNII: 9O3K93S3TK)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55264-050-01	1 in 1 BOX	05/30/2016	
1		20 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	05/30/2016	

Labeler - Sinsin Pharmaceutical Co., Ltd. (823149161)

Registrant - Sinsin Pharmaceutical Co., Ltd. (823149161)