

SCADEXE- allantoin, lidocaine, petrolatum patch
Patchwerx Labs, Inc.

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.

SCADEXE PATCH

Active Ingredient Section

Active Ingredient

Allantoin 2.00 %

Lidocaine 4.00 %

Petrolatum 30.00 %

ASK DOCTOR SECTION

Stop use and ask a doctor if condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days

DO NOT USE SECTION

- on deep or puncture wounds, animal bites, serious burns
- in large quantities, particularly over raw surfaces or blistered areas

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children. If pregnant or breastfeeding, contact physician prior to use

PREGNANCY OR BREAST FEEDING

If pregnant or breastfeeding, contact physician prior to use

PURPOSE

- Temporarily protects minor cuts , scrapes and burns
- Temporary relief of pain associated with minor cuts, scrapes and minor skin irritations

QUESTIONS

For questions or comments please call 800-317-2910

STOP USE SECTION

Stop use if condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days.

WHEN USING SECTION

How to apply

- clean and dry affected area
- remove mesh from backing and apply to affected area
- use only one mesh at a time, and maximum of four mesh / day
- leave mesh on affected area for up to 8 hours
- children under 12 should consult

Package Label

NDC 69329-040-30

Scadexe Patch

Active ingredient	Purpose
Atlatanin 2.00%	Skin Protectant
Lidocaine 4.00%	Topical Anesthetic
Pibrolatum 30.00%	Skin Protectant

Uses

- Temporarily protects minor cuts, scrapes and burns
- Temporarily relief of pain associated with minor cuts, scrapes and minor skin irritations

Warnings
For external use only

Do not use

- on deep or puncture wounds, animal bites, serious burns
- in large quantities, particularly over raw surfaces or blistered areas

When using this product

- avoid contact with 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 pregnant or breast feeding, contact physician prior to use

Directions

How to apply

- clean and dry affected area
- remove mesh from backing and apply to affected area
- use only one mesh at a time, and maximum of four mesh/day
- leave mesh on affected area for up to 8 hours
- do not use mesh for longer than 5 consecutive days
- children under 12 should consult physician prior to use

Other information store below 25°C (77°F), avoid direct sunlight

Other ingredients vitamin E, onion extract

Lot 201511160
Exp 12/17

Manufactured for
Patchwrx Labs, Inc
Las Vegas, NV 89118

For Questions or Comments
please call 1-800-317-2910

Made in China Patent Pending

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Dosage and Administration

These highlights do not include all the information needed to use

Warnings

Stop use if condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days.

Do not use if pregnant.

Keep away from Children

Inactive Ingredients

These highlights do not include all the information needed to use

ONION

ALPHA-TOCOPHEROL

Indications and usage

SCADEXE

allantoin, lidocaine, petrolatum patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69329-040
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98P200987)	LIDOCAINE HYDROCHLORIDE	4 g in 100 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	30 g in 100 g
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ONION (UNII: 492225Q21H)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69329-040-30	30 in 1 BOX		
1		10 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/15/2015	

Labeler - Patchwerx Labs, Inc. (079584480)

Revised: 4/2015

Patchwerx Labs, Inc.