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

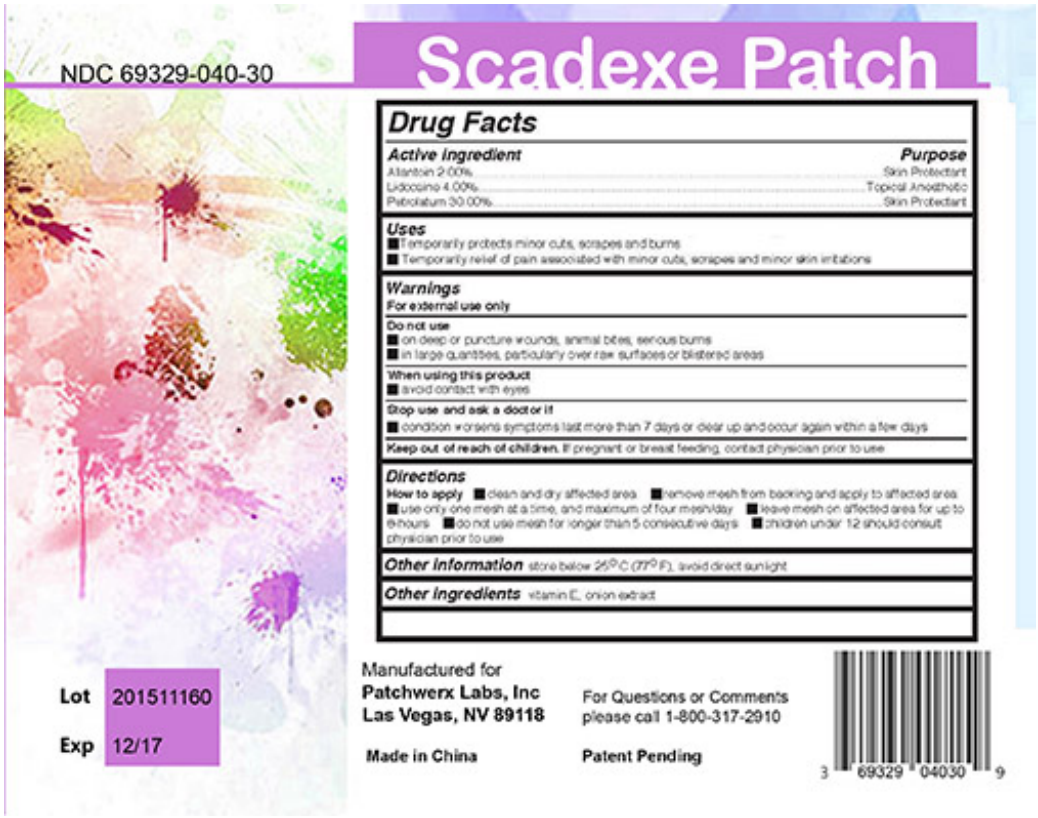
Stop use if condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days.

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



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:98PI200987)	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)

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