ELITE PAIN RELIEF- allantoin, lidocaine, petrolatum patch
Meds Direct Rx, 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.

Elite Pain Relief Patch

ACTIVE INGREDIENTS:

Allantoin 2.00%

Lidocaine 4.00%

Petrolatum 30.00%

Skin Protectant

Topical Anesthetic

SkinProtectant

USES:

Temporarily protects minor cuts, scrapes and burns

Temporary relief of pain associated with minor cuts, scrapes and minor skin irritations

WARNINGS:

•For external use only.

•Avoid contact with eyes.

•Stop use and ask a doctor if condition worsens, or 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, or serious burns.

•If pregnant or breast feeding, contact physician prior to use.

• Do not use in large quantities, particularly over raw surfaces or blistered areas.

KEEP OUT OF REACH OF CHILDREN

DIRECTIONS:

•Clean and dry affected area

•Remove mesh from backing and apply to affected area

•Use only one mesh at a time, and maximum of 4 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

INACTIVE INGREDIENTS:

Vitamin E, Onion Extract, Dihydroxyaluminum Aminoacetate, Disodium Edetate, Gelatin, Glycerin, Kaolin, Methylparaben, Polyacrylic Acid, Polyvinyl Alcohol, Propylene Glycol, Propylparaben, Sodium Polyacrylate, D-Sorbitol, Tartaric Acid, Urea, Sodium Carboxymethylcellulose

Store below 25° degrees. Avoid direct sunlight.

Manufactured For:

Meds Direct Rx, Inc

882 Third Avenue 1Oth Floor Suite 1000

Brooklyn, NY 11232

Questions or Comments call 855-480-MEDS

Made in China

Package Labeling

ELITE PAIN RELIEF

allantoin, lidocaine, petrolatum patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69418-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	2 g in 100 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	30 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:69418-004-15	15 g in 1 PATCH; 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	05/05/2015	

Labeler - Meds Direct Rx, Inc. (064053428)

Establishment

Name	Address	ID/FEI	Business Operations
Meds Direct Rx, Inc.		064053428	relabel(69418-004) , repack(69418-004)

Establishment

Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech Co. Ltd		529128763	manufacture(69418-004)

Revised: 11/2015 Meds Direct Rx, Inc.