SKULLDUGGERY PAIN RELIEF AND SKIN PROTECTION FOR TATTOOS- lanolin, petrolatum and lidocaine

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.

Skullduggery Pain Relief and Skin Protection for Tattoos

LIDOCAINE 4%

Drug Facts

Active ingredient

Lidocaine 4%

Purpose

Pain Reliever

Use

For temporary relief of pain associated with minor skin irritations due to tattooing, piercing, and hair removal

Warnings

For external use only.

Avoid contact with eyes

Do not use

- if you are allergic to any ingredient in lidocaine cream or to similar medicines (for example, local anesthetics such as benzocaine)
- in large quantities, particulary over raw surfaces or blistered areas

Ask a doctor before use if you have had an allergic reaction (for example, rash, hives, dizziness) to any anesthetic medicine

Stop use and ask a doctor if

- you develop a persistant rash
- condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days

Stop use and ask a doctor if

- you develop a persistent rash
- side effects occur, condition worsens, or
- symptoms persist for more than 7 days

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

Directions

- for adult use only
- before procedure, apply a small amount of 4% Lidocaine to affected area and allow to dry. Application may be repeated up to 4 times daily.

Other information

- see bottom of carton for lot number and expiration date
- store at 15 to 30°C (59 to 86°F)
- do not use if carton is damaged or open
- do not use if seal on tube is punctured or missing

Inactive ingredients

aloe barbadensis leaf juice, arginine, benzophenone-4, cetyl alcohol, dimethyl sulfoxide, melaleuca alternifolia (tea tree) leaf oil, phenoxyethanol (and) caprylyl glycol (and) potassium sorbate (and) water (and) hexylene glycol, purified water, simmondsia chinensis (jojoba) seed oil, sodium polyacrylate, stearic acid

Questions or comments?

866-323-0107 or www.getskullduggery.com

VITAMIN A&D

Drug Facts

Active ingredients	Purpose
Lanolin 15.5%	Skin protectant
Petrolatum 53.4%	Skin protectant

Use

Temporarily protects and helps relieve minor skin irritation due to tattooing, piercing, and hair removal

Warnings

For external use only.

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

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: 800-222-1222.

Direction

After procedure, apply A&D Ointment as needed to affected skin.

Other information

- see bottom of carton for lot number and expiration date
- store at 15 to 30°C (59 to 86°F)
- do not use if carton is damaged or open
- do not use if seal on tube is punctured or missing

Inactive ingredients

beeswax, cod liver oil (contains vitamin A & vitamin D), fragrance, mineral oil, microcrystalline wax

Questions or comments?

866-323-0107 or www.getskullduggery.com

This product is manufactured and distributed by NatureplexTM.

PRINCIPAL DISPLAY PANEL - Kit Carton

SKULLDUGGERY

NDC# 67234-047-01

For Temporary Pain Relief associated with Tattoos, Piercing, and Hair Removal

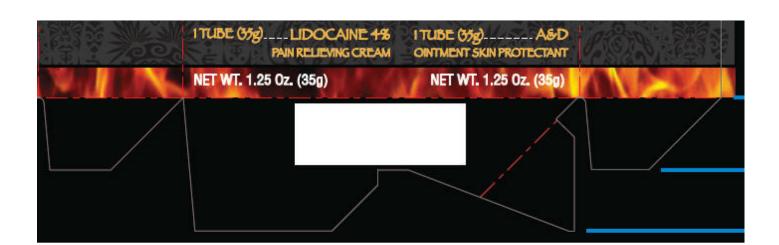
1 TUBE (35g) LIDOCAINE 4% PAIN RELIEVING CREAM

NET WT. 1.25 Oz. (35g)

1 TUBE (35g) A&D OINTMENT SKIN PROTECTANT

NET WT. 1.25 Oz. (35g)





LIDOCAINE 4%

Drug Facts

Active ingredient Lidocaine 4%.....

Purpose Pain Reliever

For temporary relief of pain associated with minor skin irritations due to tattooing, piercing,

Warnings For external use only. Avoid contact with eyes

Do not use

- if you are altergic to any ingredient in fidocaine cream or to similar medicines (for example, local anesthetics such as benzocaine)
- in large quantities, particulary over raw surfaces or blistered areas

Ask a doctor before use if you have had an allergic reaction (for example, rash, hives, dizziness) to any anesthetic medicine

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Stop use and ask a doctor if you develop a persistent rash

Drug Facts (continued)

- side effects occur, condition worsens, or symptoms persist for more than 7 days

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

Directions

- m for adult use only
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Other information

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Inactive incredients

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Questions or comments? 866-323-0107 or www.getskullduggery.com

VITAMIN A&D

Drug Facts

Active ingredients Purpose Skin protectant Lanolin 15.5% Petrolatum 53.4%.....Skin protectant

Temporarily protects and helps relieve minor skin irritation due to tattooing, piercing, and hair removal

Warnings

For external use only. Avoid contact with eye

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

Drug Facts (continued)

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

Direction

After procedure, apply A&D Ointment as needed to affected skin.

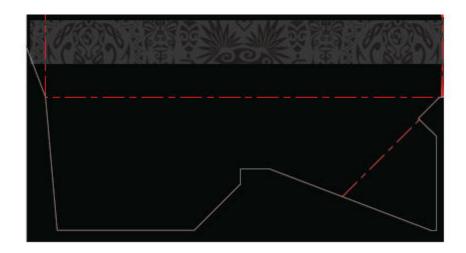
Other information

- see bottom of carton for lot number and expiration date
- store at 15 to 30°C (59 to 86°F) do not use if carton is damaged or open
- do not use if seal on tube is punctured or missing

Inactive ingredients beeswax, cod liver oil (contains vitamin A & vitamin D), fragrance, mineral oil, microcrystalline wax

Questions or comments?

866-323-0107 or www.getskullduggery.com



SKULLDUGGERY PAIN RELIEF AND SKIN PROTECTION FOR TATTOOS

lanolin, petrolatum and lidocaine kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67234-047

Packaging

ı	rackaging					
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1 NDC:67234-047-01	1 in 1 CARTON	06/04/2003			

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	35 g
Part 2	1 TUBE	35 g

Part 1 of 2

A AND D

lanolin and petrolatum ointment, augmented

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Lanolin (UNII: 7EV65EAW6H) (Lanolin - UNII:7EV65EAW6H)	Lanolin	155 mg in 1 g		
Petrolatum (UNII: 4T6H12BN9U) (Petrolatum - UNII:4T6H12BN9U)	Petro latum	534 mg in 1 g		

Inactive Ingredients				
Ingredient Name	Strength			
YELLOW WAX (UNII: 2ZA36H0S2V)				
COD LIVER OIL (UNII: BBL281NWFG)				
LIGHT MINERAL OIL (UNII: N6K5787QVP)				
MICRO CRYSTALLINE WAX (UNII: XOF597Q3KY)				

ı	Pa	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1		35 g in 1 TUBE; Type 8: Possible Combination Based on Cross Labeling of Separate Products (Temporary Type)			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part347	06/04/2003			

Part 2 of 2

LIDOCAINE PAIN RELIEVING

lidocaine cream

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Lidocaine (UNII: 98PI200987) (Lidocaine - UNII:98PI200987)	Lidocaine	40 mg in 1 g		

Inactive Ingredients			
Ingredient Name	Strength		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
SULISOBENZONE (UNII: 1W6L629B4K)			
CETYL ALCOHOL (UNII: 936JST6JCN)			
DIMETHYL SULFOXIDE (UNII: YOW8 V9698H)			
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)			
ARGININE (UNII: 94ZLA3W45F)			
WATER (UNII: 059QF0KO0R)			
JOJOBA OIL (UNII: 724GKU717M)			
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)			
STEARIC ACID (UNII: 4ELV7Z65AP)			

TEA TREE OIL (UNII: VIF565UC2G)

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1		35 g in 1 TUBE; Type 8: Possible Combination Based on Cross Labeling of Separate Products (Temporary Type)		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part348	12/25/2009			
Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part347	06/04/2003			

Labeler - Natureplex, LLC (062808196)

Establishment						
Name	Address	ID/FEI	Business Operations			
Natureplex LLC		062808196	MANUFACTURE(67234-047)			

Revised: 4/2017 Natureplex, LLC