# KENDRA SKIN PROTECTION AND PAIN RELIEF FOR HAIR REMOVAL- 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.

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#### Kendra SKIN PROTECTION & PAIN RELIEF FOR HAIR REMOVAL

#### A&D OINTMENT

#### **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

### When using this product

do not get into eyes

# 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 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 immediately: 1-800-222-1222.

#### **Directions**

• After procedure, apply A&D Skin Protectant 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, light mineral oil, microcrystalline wax

### **Questions or Comments?**

1-866-323-0107 or www.kendracollection.com

#### **4% LIDOCAINE**

**Drug Facts** 

# Active ingredient

Lidocaine 4%

# Purpose

Pain Relieving Cream

#### 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 the eyes

#### Do Not Use

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

#### Ask a doctor before use

• if you have had an allergic reaction (e.g., rash, hives, dizziness) to any anesthetic medicine

#### Stop use and ask a doctor if

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

**Keep out of reach of children.** If swallowed, get medical help, or contact a Poison Control Center immediately: 1-800-222-1222.

#### **Directions**

- For adult use only.
- Before procedure, apply a small amount of pain relieving cream 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, benzophenone-4, cetyl alcohol, dimethyl sulfoxide, jeecide cap-5, L-arginine, purified water, simmondsia chinesis (jojoba) seed oil, sodium polyacrylate, stearic acid, tea tree oil

# **Questions or Comments?**

1-866-323-0107 or www.kendracollection.com

This product is manufactured and distributed by Natureplex<sup>TM</sup>.

#### PRINCIPAL DISPLAY PANEL - Kit Carton

NDC# 67234-048-01

#### **KENDRA**

PAIN RELIEF & SKIN PROTECTANT
A&D OINTMENT SKIN PROTECTANT
1 TUBE NET WT. 1.75 Oz. (49.6g)
LIDOCAINE 4% PAIN RELIEVING CREAM
1 TUBE NET WT. 1.75 Oz. (49.6g)

# KENDRA

NDC# 67234-048-01

KENDRA

PAIN RELIEF & SKIN PROTECTANT

# A&D OINTMENT SKIN PROTECTANT 1 TUBE NET WT. 1.75 Oz. (49.6g)

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# A&D OINTMENT

# **Drug Facts**

Active ingredients	Purpose
Lanolin 15.5%	Skin protectant
Petrolatum 53.4%	

#### 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 persist for 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.kendracollection.com

\*This product is manufactured and distributed by Natureplex™.



# 4% LIDOCAINE

# **Drug Facts**

#### 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, particularly 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 persistent rash
- condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few 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

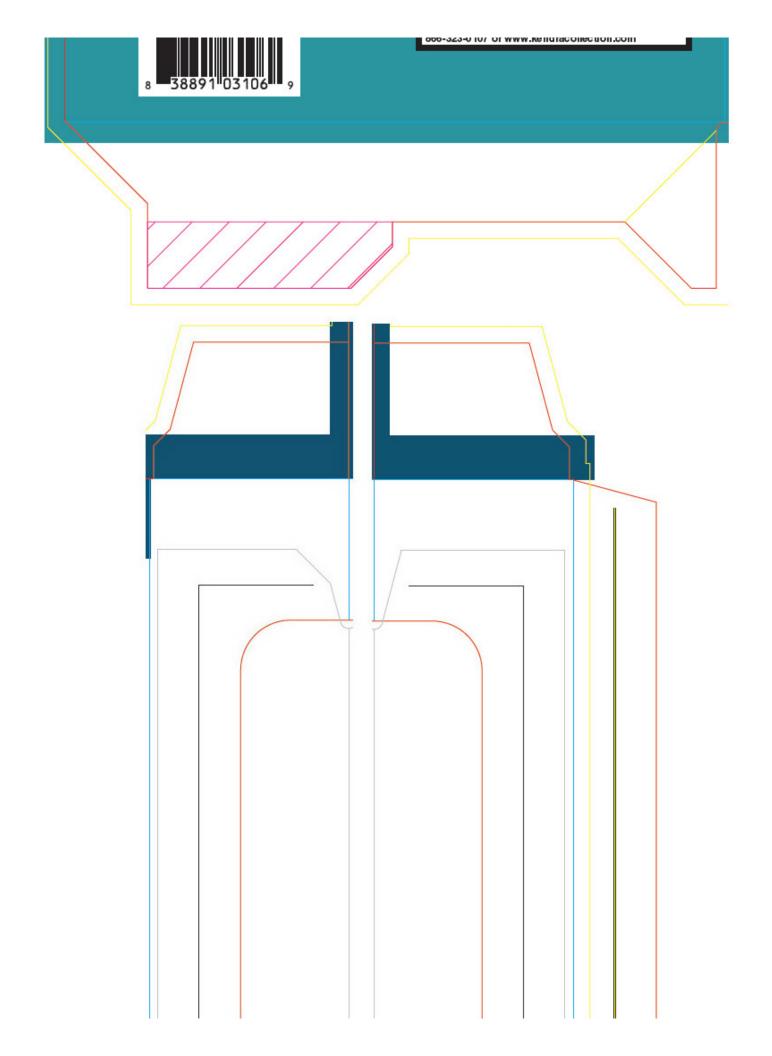
- see bottom of carton for lot number and expiration date
- store at 15 to 30°C (59 to 86°F)
- do not use if carton is damaged or open
- do not use if seal on tube is punctured or missing

#### 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?

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# KENDRA SKIN PROTECTION AND PAIN RELIEF FOR HAIR REMOVAL

lanolin, petrolatum and lidocaine kit

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67234-048

**Packaging** 

l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:67234-048-01	1 in 1 CARTON	06/04/2003	

# **Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	28 g
Part 2	1 TUBE	28 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)	Pe tro la tum	534 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
COD LIVER OIL (UNII: BBL28 1NWFG)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
MICRO CRYSTALLINE WAX (UNII: XOF597Q3KY)	

ı	Pa	ckagin	g		
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1		28 g in 1 TUBE; Type 8: Possible Combination Based on Cross Labeling of Separate Products (Temporary Type)		

<b>Marketing Info</b>	rmation		
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 Lidocaine (UNII: 98PI200987) (Lidocaine - UNII:98PI200987) Lidocaine (UNII: 98PI200987) (Lidocaine - UNII:98PI200987)

Inactive Ingredients		
	Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
SULISOBENZONE (UNII: 1W6L629B4K)		
CETYL ALCOHOL (UNII: 936JST6JCN)		

<b>DIMETHYL SULFO XIDE</b> (UNII: YOW8 V9698 H)	
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	Pá	ackagin	g		
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1		28 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 Infor	mation		
Marketing Infor	mation Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Marketing Infor	mation		

# Labeler - Natureplex, LLC (062808196)

Establishment			
Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(67234-048)

Revised: 10/2017 Natureplex, LLC