0.025% CAPSAICIN PATCH- capsaicin pain relief patch, capsaicin pain relief strip patch

4% LIDOCAINE PAIN RELIEF PATCH- lidocaine pain relief patch patch

5% MENTHOL PAIN RELIEF PATCH- pain relief patch patch

4% LIDOCAINE PLUS 1% MENTHOL PAIN RELIEF PATCH- pain relief patch, pain relief strip patch

Kookare Technology Co., Ltd.

0.025% Capsaicin Patch NDC: 84205-001-00

SIZE: 135×175mm



Front Back

Directions

appy 1 patch at a time to affect area, not more than 3 to 4 times daily remove patch from the skin after a most 8-hour application



Front Back

Warnings



Front Back

Do not use

- more than 1 patch at a time
- on wounds or damaged skin
- with a heating pad
- if you are allergic to any ingredients of this product

When using this product

- · use only as directed
- avoid contact with the eyes, mucous membranes or rashes
- do not bandage tightly

Stop use and ask a doctor if

- localized skin reactions occur, such as rash, itching, redness, irritation, pain, swelling and blistering
- condition worsen
- symptoms persist form more than 7 days
- symptoms clear up and occur again within a few days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Posison Control Center right away.

Inactive ingredient

Glycerin, sodium polyacrylate, Carboxymethylcellulose sodium, Dihydroxyaluminium Aminoacetate, disodium Ethylenediaminetetraacetic acid, kaolin, water, tartaric acid, polyvinylpyrrolidone 90, glaydant (DMDM HYDANTOIN), propylene glycol, Polysorbate 80.

Directions

Directions

Adult and children 12 years of age and over:

- Clean and dry affected area
- Remove film from patch and apply to the skin (see illustration)
- Apply 1 patch at a time to affected area, not more than 3 to 4 times daily
- Remove patch from the skin after at most 8-hour application

Children under 12 years of age: consult a doctor

Warnings

Keep out of reach of children. If swallowed, get medical help or contact a Posison Control Center right away.

Purpose

Topical anesthetic

4% Lidocaine Pain Relief Patch NDC: 84205-002-00



Directions

appy 1 patch at a time to affect area, not more than 3 to 4 times daily remove patch from the skin after a most 8-hour application

Warnings

Warnings (For external use only)

Do not use

- more than 1 patch at a time
- on wounds or damaged skin
- with a heating pad
- if you are allergic to any ingredients of this product

When using this product

- use only as directed
- avoid contact with the eyes, mucous membranes or rashes
- do not bandage tightly

Stop use and ask a doctor if

• localized skin reactions occur, such as rash, itching, redness, irritation, pain, swelling

- and blistering
- condition worsen
- symptoms persist form more than 7 days
- symptoms clear up and occur again within a few days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Posison Control Center right away.

Inactive ingredients

Glycerin, propylene glycol, sodium polyacrylate, Carboxymethylcellulose sodium, disodium Ethylenediaminetetraacetic acid, kaolin, Polysorbate 80, water, tartaric acid, glaydant(DMDM HYDANTOIN), DihydroxyaluminiumAminoacetate, polyvinylpyrrolidone 90.

Directions

Directions

Adult and children 12 years of age and over:

- Clean and dry affected area
- Remove film from patch and apply to the skin (see illustration)
- Apply 1 patch at a time to affected area, not more than 3 to 4 times daily
- Remove patch from the skin after at most 8-hour application

Children under 12 years of age: consult a doctor

Warnings

Keep out of reach of children. If swallowed, get medical help or contact a Posison Control Center right away.

Purpose

Topical anesthetic

4% Lidocaine plus 1% Menthol Pain Relief Patch NDC: 84205-003-00



Directions

appy 1 patch at a time to affect area, not more than 3 to 4 times daily remove patch from the skin after a most 8-hour application

Warnings

Warnings (For external use only)

Do not use

- more than 1 patch at a time
- on wounds or damaged skin
- with a heating pad
- if you are allergic to any ingredients of this product

When using this product

- use only as directed
- avoid contact with the eyes, mucous membranes or rashes
- do not bandage tightly

Stop use and ask a doctor if

• localized skin reactions occur, such as rash, itching, redness, irritation, pain, swelling

- and blistering
- condition worsen
- symptoms persist form more than 7 days
- symptoms clear up and occur again within a few days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Posison Control Center right away.

Inactive ingredients

Glycerin, propylene glycol, sodium polyacrylate, Carboxymethylcellulose sodium, Dihydroxyaluminium Aminoacetate, kaolin, Ethyl Alcohol, water,tartaric acid, polyvinylpyrrolidone 90, glaydant(DMDM HYDANTOIN), disodium Ethylenediaminetetraacetic acid, Polysorbate 80.

Directions

Directions

Adult and children 12 years of age and over:

- Clean and dry affected area
- Remove film from patch and apply to the skin (see illustration)
- Apply 1 patch at a time to affected area, not more than 3 to 4 times daily
- Remove patch from the skin after at most 8-hour application

Children under 12 years of age: consult a doctor

Warnings

Keep out of reach of children. If swallowed, get medical help or contact a Posison Control Center right away.

Purpose

Topical anesthetic

0.025% Capsaicin Patch NDC: 84205-001-01



Do not use

Do not use more than 1 patch at a time



Warnings



Inactive ingredients

Glycerin, sodium polyacrylate, Carboxymethylcellulose sodium, Dihydroxyaluminium Aminoacetate, disodium Ethylenediaminetetraacetic acid, kaolin, water, tartaric acid, polyvinylpyrrolidone 90, glaydant (DMDM HYDANTOIN), propylene glycol, Polysorbate 80.

Directions

Directions

Adult and children 12 years of age and over:

- Clean and dry affected area
- Remove film from patch and apply to the skin (see illustration)
- Apply 1 patch at a time to affected area, not more than 3 to 4 times daily
- Remove patch from the skin after at most 8-hour application

Children under 12 years of age: consult a doctor

Warnings

Keep out of reach of children. If swallowed, get medical help or contact a Posison Control Center right away.

Purpose

5% Menthol Pain Relief Patch NDC: 84205-004-01



Directions

appy 1 patch at a time to affect area, not more than 3 to 4 times daily remove patch from the skin after a most 8-hour application

Warnings

Warnings (For external use only)

Do not use

- more than 1 patch at a time
- on wounds or damaged skin
- with a heating pad
- if you are allergic to any ingredients of this product

When using this product

- use only as directed
- avoid contact with the eyes, mucous membranes or rashes
- do not bandage tightly

Stop use and ask a doctor if

- localized skin reactions occur, such as rash, itching, redness, irritation, pain, swelling and blistering
- condition worsen
- symptoms persist form more than 7 days
- symptoms clear up and occur again within a few days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Posison Control Center right away.

Inactive ingredients

Glycerin, sodium polyacrylate, Dihydroxyaluminium Aminoa acetate, disodium Ethylenediaminetetraacetic acid, water, tartaric acid, polyvinylpyrrolidone 90, glaydant(DMDM HYDANTOIN), Polysorbate 80, Ethyl Alcohol, Carboxymethylcellulose sodium, kaolin.

Directions

Directions

Adult and children 12 years of age and over:

- Clean and dry affected area
- Remove film from patch and apply to the skin (see illustration)
- Apply 1 patch at a time to affected area, not more than 3 to 4 times daily
- Remove patch from the skin after at most 8-hour application

Children under 12 years of age: consult a doctor

Warnings

Keep out of reach of children. If swallowed, get medical help or contact a Posison Control Center right away.

Purpose

5% Menthol Pain Relief Patch NDC: 84205-004-00

5% Menthol Pain Relief Patch NDC: 84205-004-00



Directions

appy 1 patch at a time to affect area, not more than 3 to 4 times daily remove patch from the skin after a most 8-hour application

Warnings

Warnings (For external use only)

Do not use

- more than 1 patch at a time
- on wounds or damaged skin
- with a heating pad
- if you are allergic to any ingredients of this product

When using this product

- use only as directed
- avoid contact with the eyes, mucous membranes or rashes
- do not bandage tightly

Stop use and ask a doctor if

• localized skin reactions occur, such as rash, itching, redness, irritation, pain, swelling

- and blistering
- condition worsen
- symptoms persist form more than 7 days
- symptoms clear up and occur again within a few days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Posison Control Center right away.

Inactive ingredients

Glycerin, sodium polyacrylate, Dihydroxyaluminium Aminoa acetate, disodium Ethylenediaminetetraacetic acid, water, tartaric acid, polyvinylpyrrolidone90, glaydant(DMDM HYDANTOIN), Polysorbate80, Ethyl Alcohol, Carboxymethylcellulose sodium, kaolin.

Directions

Directions

Adult and children 12 years of age and over:

- Clean and dry affected area
- Remove film from patch and apply to the skin (see illustration)
- Apply 1 patch at a time to affected area, not more than 3 to 4 times daily
- Remove patch from the skin after at most 8-hour application

Children under 12 years of age: consult a doctor

Warnings

Keep out of reach of children. If swallowed, get medical help or contact a Posison Control Center right away.

Purpose

Topical anesthetic

4% Lidocaine Pain Relief Patch NDC: 84205-002-01



Warnings

Warnings (For external use only)

Do not use

- more than 1 patch at a time
- on wounds or damaged skin
- with a heating pad
- if you are allergic to any ingredients of this product

When using this product

- use only as directed
- avoid contact with the eyes, mucous membranes or rashes
- do not bandage tightly

Stop use and ask a doctor if

- localized skin reactions occur, such as rash, itching, redness, irritation, pain, swelling and blistering
- condition worsen
- symptoms persist form more than 7 days
- symptoms clear up and occur again within a few days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Posison

Control Center right away.

Directions

appy 1 patch at a time to affect area, not more than 3 to 4 times daily remove patch from the skin after a most 8-hour application

Inactive ingredients

Glycerin, propylene glycol, sodium polyacrylate, Carboxymethylcellulose sodium, disodium Ethylenediaminetetraacetic acid, kaolin, Polysorbate 80, water, tartaric acid, glaydant(DMDM HYDANTOIN), DihydroxyaluminiumAminoacetate, polyvinylpyrrolidone 90.

Directions

Directions

Adult and children 12 years of age and over:

- Clean and dry affected area
- Remove film from patch and apply to the skin (see illustration)
- Apply 1 patch at a time to affected area, not more than 3 to 4 times daily
- Remove patch from the skin after at most 8-hour application

Children under 12 years of age: consult a doctor

Warnings

Keep out of reach of children. If swallowed, get medical help or contact a Posison Control Center right away.

Purpose

Topical anesthetic

4% Lidocaine plus 1% Menthol Pain Relief Patch NDC: 84205-003-01



Directions

appy 1 patch at a time to affect area, not more than 3 to 4 times daily remove patch from the skin after a most 8-hour application

Warnings

Warnings (For external use only)

Do not use

- more than 1 patch at a time
- on wounds or damaged skin
- with a heating pad
- if you are allergic to any ingredients of this product

When using this product

- use only as directed
- avoid contact with the eyes, mucous membranes or rashes
- do not bandage tightly

Stop use and ask a doctor if

- localized skin reactions occur, such as rash, itching, redness, irritation, pain, swelling and blistering
- condition worsen

- symptoms persist form more than 7 days
- symptoms clear up and occur again within a few days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Posison Control Center right away.

Inactive ingredients

Glycerin, propylene glycol, sodium polyacrylate, Carboxymethylcellulose sodium, Dihydroxyaluminium Aminoacetate, kaolin, Ethyl Alcohol, water,tartaric acid, polyvinylpyrrolidone 90, glaydant(DMDM HYDANTOIN), disodium Ethylenediaminetetraacetic acid, Polysorbate 80.

Directions

Directions

Adult and children 12 years of age and over:

- Clean and dry affected area
- Remove film from patch and apply to the skin (see illustration)
- Apply 1 patch at a time to affected area, not more than 3 to 4 times daily
- Remove patch from the skin after at most 8-hour application

Children under 12 years of age: consult a doctor

Warnings

Keep out of reach of children. If swallowed, get medical help or contact a Posison Control Center right away.

Purpose

Topical anesthetic

0.025% CAPSAICIN PATCH

capsaicin pain relief patch, capsaicin pain relief strip patch

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84205-001	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07044R1ZM) (CAPSAICIN - UNII:S07044R1ZM)	CAPSAICIN	2.5 mg in 10 g

Inactive Ingredients	
Ingredient Name	Strength

TARTARIC ACID (UNII: W48881119H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
KAOLIN (UNII: 24H4NWX5CO)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)	
WATER (UNII: 059QF0KO0R)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics	
Color	Score
Shape	Size
Flavor	Imprint Code
Contains	

P	ackaging			
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84205- 001-00	1 g in 1 PATCH; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug	02/04/2024	
2	NDC:84205- 001-01	5 in 1 BOX	02/04/2024	
2	NDC:84205- 001-00	1 g in 1 PATCH; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug		



Front	Back
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Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date				
OTC Monograph Drug	M017	02/04/2024		

4% LIDOCAINE PAIN RELIEF PATCH

lidocaine pain relief patch patch

Product Information					
Product Type	HUMAN OTC DRUG	Item Cod	e (Source)	NDC:	84205-002
Route of Administration	TOPICAL				
Active Ingredient/Active Moiety					
Ingredient Name Basis of Strength Strength					
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) LIDOCAINE 0.4 g in 10 g			0.4 g in 10 g		

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
KAOLIN (UNII: 24H4NWX5CO)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
TARTARIC ACID (UNII: W48881119H)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)	
WATER (UNII: 059QF0KO0R)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	

Product Characteristics	
Color	Score
Shape	Size
Flavor	Imprint Code
Contains	

P	Packaging				
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:84205- 002-01	5 in 1 BOX	02/04/2024		
1	NDC:84205- 002-00	1 g in 1 PATCH; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug			
2	NDC:84205- 002-00	1 g in 1 PATCH; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug	02/04/2024		



Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M017	02/04/2024		

5% MENTHOL PAIN RELIEF PATCH

pain relief patch patch

pani rener paren paren					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (S	ource)	NDC:84	205-004
Route of Administration	TOPICAL				
Active Ingredient/Active Moiety					
Ingredient Name Basis of Strength Strength					
MENTHOL, (+)- (UNII: C6B10E8P3	W) (MENTHOL, (+) UNII:C	6B10E8P3W)	MENTHOL, (+)-		0.5 g in 10 g

Inactive Ingredients	
Ingredient Name	Strength
TARTARIC ACID (UNII: W48881119H)	
KAOLIN (UNII: 24H4NWX5CO)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05115JN12J)	
WATER (UNII: 059QF0KO0R)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ALCOHOL (UNII: 3K9958V90M)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
POVIDONE K90 (UNII: RDH86HJV5Z)	

Product Characteristics				
Color	Score			
Shape	Size			
Flavor	Imprint Code			
Contains				

P	ackaging			
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84205- 004-00	1 g in 1 PATCH; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug	02/04/2024	
2	NDC:84205- 004-01	5 in 1 BOX	02/04/2024	
2	NDC:84205- 004-00	1 g in 1 PATCH; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug		



Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M017	02/04/2024		

4% LIDOCAINE PLUS 1% MENTHOL PAIN RELIEF PATCH

pain relief patch, pain relief strip patch

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84205-003		
Route of Administration	TOPICAL				

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.4 g in 10 g
MENTHOL, (+)- (UNII: C6B10E8P3W) (MENTHOL, (+) UNII:C6B10E8P3W)	MENTHOL, (+)-	0.1 g in 10 g

Inactive Ingredients	
Ingredient Name	Strength
KAOLIN (UNII: 24H4NWX5CO)	
WATER (UNII: 059QF0KO0R)	
TARTARIC ACID (UNII: W4888I119H)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
ALCOHOL (UNII: 3K9958V90M)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics				
Color	Score			
Shape	Size			
Flavor	Imprint Code			
Contains				

P	ackaging			
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84205- 003-00	1 g in 1 PATCH; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug	02/04/2024	
2	NDC:84205- 003-01	5 in 1 BOX	02/04/2024	
2	NDC:84205- 003-00	1 g in 1 PATCH; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug		



Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M017	02/04/2024		

Labeler - Koolcare Technology Co., Ltd. (602479389)

Registrant - Koolcare Technology Co., Ltd. (602479389)

Establishment			
Name	Address	ID/FEI	Business Operations
Koolcare Technology Co., Ltd.		602479389	manufacture(84205-001, 84205-002, 84205-004, 84205-003)

Revised: 4/2024 Koolcare Technology Co., Ltd.