

SINSINPAS LIDOCAINE PAIN RELIEVING- lidocaine patch
Sinsin Pharmaceutical Co., Ltd.

SINSINPAS LIDOCAINE PAIN RELIEVING PATCH

Active Ingredients

Lidocaine 4%

Purpose

Topical Anesthetic

Keep out of reach of children or pets

Keep out of reach of children or pets.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222)

Uses

For the temporarily relief of minor pain

Warnings

For external use only

Do not use

- more than 1 patch at a time
- on broken, irritated, or swollen skin
- on puncture wounds
- for more than one week without consulting a doctor

When using this product

- use only as directed. Read and follow all direction and warning on this label
- Avoid contact with the eyes or mucous membranes
- Do not apply to broken, damaged, or irritated skin
- Do not bandage tightly or apply local heat (such as heating pads) to the area of use
- Rare cases of serious burns have been reported with products of this type
- Do not use with other topical analgesics
- Keep children and pets away from used or disposed patch.
- Used patches still contain the drug product that can produce serious adverse effects if a child or pet chews or ingests this product.

Directions

Adults and children 12 years of age and over:

- clean and dry affected area
- remove film from patch by gently pulling apart from corner
- carefully apply to affected area
- once patch is positioned, press firmly to adhere to skin
- use only one patch at a time for up to 12 hours

Children under 12 years of age: consult a professional

Inactive Ingredients

butylated hydroxytoluene

carboxymethylcellulose sodium

glycerin

edetate disodium

isopropyl myristate

kaolin

magnesium aluminosilicate

methyl acrylate and 2-ethylhexyl acrylate copolymer aqueous emulsion (mixture)

methyl paraben

polyacrylic acid

polysorbate 80

propylene glycol

propyl paraben

purified water

sodium polyacrylate

sorbitan sesquioleate

tartaric acid

urea

SINSINPAS LIDOCAINE PAIN RELIEVING PATCH



SINSINPAS LIDOCAINE PAIN RELIEVING

lidocaine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55264-106
Route of Administration	CUTANEOUS, TOPICAL, TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	560 mg in 14 g

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	280 mg in 14 g
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
GLYCERIN (UNII: PDC6A3C0OX)	3500 mg in 14 g

Product Characteristics

Color	white	Score	
Shape	RECTANGLE	Size	14mm

Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55264-106-03	5 in 1 BOX	05/25/2017	
1	NDC:55264-106-02	1 in 1 POUCH		
1	NDC:55264-106-01	14 g in 1 PATCH; Type 0: Not a Combination Product		

SINSINPAS
NDC NO. 55264-106-03

IMPROVED ADHESION

Maximum Strength
LIDOCAINE
4% Pain Relieving Patch

Targets pain for quick relief
Penetrates nerve receptors to numb and desensitize
Long lasting and unscented
Easy to apply

5 PATCHES
3.93 in X 5.51 in (10 cm X 14 cm) EACH

ODOR FREE

Maximum Strength
LIDOCAINE
4% Pain Relieving Patch

DRUG FACTS
Active ingredient: Lidocaine 4% Purpose: Topical anesthetic

Uses For temporary relief of minor pain

Warnings
For external use only

Do not use
more than 1 patch at a time on broken, irritated, or swollen skin on puncture wounds for more than one week without consulting a doctor

When using this product
Use only as directed. Read and follow all directions and warnings on this label. Avoid contact with the eyes or mucous membranes. Do not apply to broken, damaged, or irritated skin. Do not bandage tightly or apply local heat (such as heating pads) to the area of use. Rare cases of serious burns have been reported with products of this type. Do not use with other topical anesthetics. Keep children and pets away from used or disposed patch. Used patches still contain the drug product that can produce serious adverse effects if a child or pet chews or ingests this product.

Stop use and ask a doctor if
condition worsens, irritation develops, redness is present, symptoms persist for more than 7 days or clear up and occur again within a few days, any signs of skin injury appear at the site of the product application such as pain, swelling, bruising, or blistering.

If pregnant or breastfeeding, ask a physician before use.

Keep out of reach of children or pets.
If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Other information
avoid storing in direct sunlight protect product from excess moisture store at room temperature. Do not exceed 85° Fahrenheit, 30° Celsius.

Directions Adults/children 12 years of age and over: clean and dry affected area, remove film from patch by gently pulling apart from corner, carefully apply to affected area, once patch is positioned, press firmly to adhere to skin, use only one patch at a time for up to 12 hours. Children under 12 years of age: consult a healthcare professional.

Inactive ingredients
Butylated hydroxytoluene, Carboxymethylcellulose Sodium, Disodium Edetate Hydrate, Concentrated Glycerin, Isopropyl Myristate, Kaolin, Magnesium Aluminum Silicate, Nizakole TS-620, Methylparaben, Polyacrylic acid solution, Polysorbate 80, Propylene Glycol, Propylparaben, Purified water, Sodium Polyacrylate, Sorbitan Sesquiepolesate, Tartaric Acid, Titanium Oxide, Urea, D-Sorbitol solution.

Distributed by: SINSIN Pharma America, Brea, CA 92821. Made in Korea. LOT: EXP:

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	05/25/2017	

Labeler - Sinsin Pharmaceutical Co., Ltd. (823149161)

Registrant - Sinsin Pharmaceutical Co., Ltd. (687867143)

Establishment

Name	Address	ID/FEI	Business Operations
Sinsin Pharmaceutical Co., Ltd.		687867143	manufacture(55264-106)