

PAIN RELIEVING GEL-PATCH- lidocaine patch
Shanghai Chuangshi Medical Technology (Group) Co., Ltd.

CSI, Pain Relieving Gel-Patch, Lidocaine 4%, 6 Patches

Active Ingredient

Lidocaine 4%

Purpose

Topical Anesthetic

Uses

For temporary relief of pain

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 ... if

- localized skin reactions occur, such as rash, itching, redness, irritation, pain, swelling and blistering
- Conditions worsen
- Symptoms persists for more than 7 days
- Symptoms clear up and occur again within a few days

... ask a doctor if

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

- Symptoms persists for 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 Poison Control Center right away.

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

Dosage forms & strengths

This is a strip, patch dosage form.

The active ingredient strength is 4% w/w.

One patch one time, no more than 8 hours one time.

Other information

- Avoid storing product in direct sunlight
- Protect product from excessive moisture

Inactive Ingredients

Dihydroxyaluminum Aminoacetate, Edetate Disodium, Glycerin, Hydroxyacetophenone, Kaolin, Polysorbate 80, Propylene Glycol, Polyacrylic Acid, PVP, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide, Water

Questions or Comments

86-21-31166566 webmaster@csigroup.com.cn

Package label. Principal display panel



PAIN RELIEVING GEL-PATCH

lidocaine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73557-159
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.04 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
GLYCERIN (UNII: PDC6A3C0OX)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
KAOLIN (UNII: 24H4NWX5CO)	
TARTARIC ACID (UNII: W4888119H)	
WATER (UNII: 059QF0KO0R)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73557-159-06	6 in 1 BOX	11/01/2024	
1	NDC:73557-159-01	12 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 Drug	M017	11/01/2024	

Labeler - Shanghai Chuangshi Medical Technology (Group) Co., Ltd. (546872672)

Registrant - Shanghai Chuangshi Medical Technology (Group) Co., Ltd. (546872672)

Establishment

Name	Address	ID/FEI	Business Operations
Shanghai Chuangshi Medical Technology (Group) Co., Ltd.		546872672	manufacture(73557-159) , label(73557-159)

Revised: 11/2024

Shanghai Chuangshi Medical Technology (Group) Co., Ltd.