OVERNIGHT RELIEF GEL-PATCH- menthol patch
Shanghai Chuangshi Medical Technology (Group) Co., Ltd.

CSI MENTHOL OVERNIGHT RELIEF GEL-PATCH, 5 Patches

Active ingredient

Menthol 5% w/w ..... Purpose: Topical analgesic

Purpose

Topical analgesic

Uses

Temporarily relieves minor aches and pains of muscles and joints associated with:

- simple backache
- arthrits
- strains
- bruises
- sprains

Warnings

For external use only

When using this prudocts:

• use only as directed
• avoid contact with eyes or on mucous membranes
• do not apply to wounds or damaged skin
• do not apply to irritated skin or if excessive irritation develops
• do not bandage tightly or use with heating pad or device

Stop use and ask a doctor if:
• you experience pain, swelling or blistering of the skin
• condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days
• arthritic pain persists for more than 10 days, or redness is present

If pregnant or breastfeeding, ask a health professional before use.

Keep out of reach of children. If accidentally ingested, get medical help or contact a Poison Control Center immediately

Ask doctor

Stop use and ask a doctor if:
• you experience pain, swelling or blistering of the skin

• condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days
• arthritic pain persists for more than 10 days, or redness is present

If pregnant or breastfeeding, ask a health professional before use.

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Do not use

• do not apply to wounds or damaged skin
• do not apply to irritated skin or if excessive irritation develops
• do not bandage tightly or use with heating pad or device

Stop use

Stop use and ask a doctor if: Burning disconfort or excessive skin irritation develops, condition worsens, or if symptoms persist for more than 7 days, or clear up and occur again within a few days

Pregnancy or breast feeding

If pregnant or breastfeeding, ask a health professional before use.

Keep out of reach of children

If accidentally ingested, get medical help or contact a Poison Control Center immediately

Directions

• adults and children 12 years of age and older: Clean and dry affected area, pop apart and partially peel back protective film and apply exposed gel-patch to site of pain. Carefully remove remaining film while pressing the gel-patch to skin and leave in place for up to 8 hours. Use on affected areas not more than 3 to 4 times daily.
• children under 12 years of age: consult a physician
• wash hands after use with cool water

Dosage forms & strengths

This is patch dosage form.

The active ingredient strength is 5%.

Inactive ingredients

Water, Glycerin, Polyacrylic Acid, Propylene Glycol, Sodium Polyacrylate, Mineral Oil, Lavender Essential Oil, Polysorbate 80, PVP, Petrolatum, Dihydroxyaluminum Aminoacetate, Edetate Disodium, Kaolin, Carboxymethylcellulose Sodium, Titanium Dioxide, L-Tartaric Acid, Benzalkonium Chloride, Lauralkonium Chloride

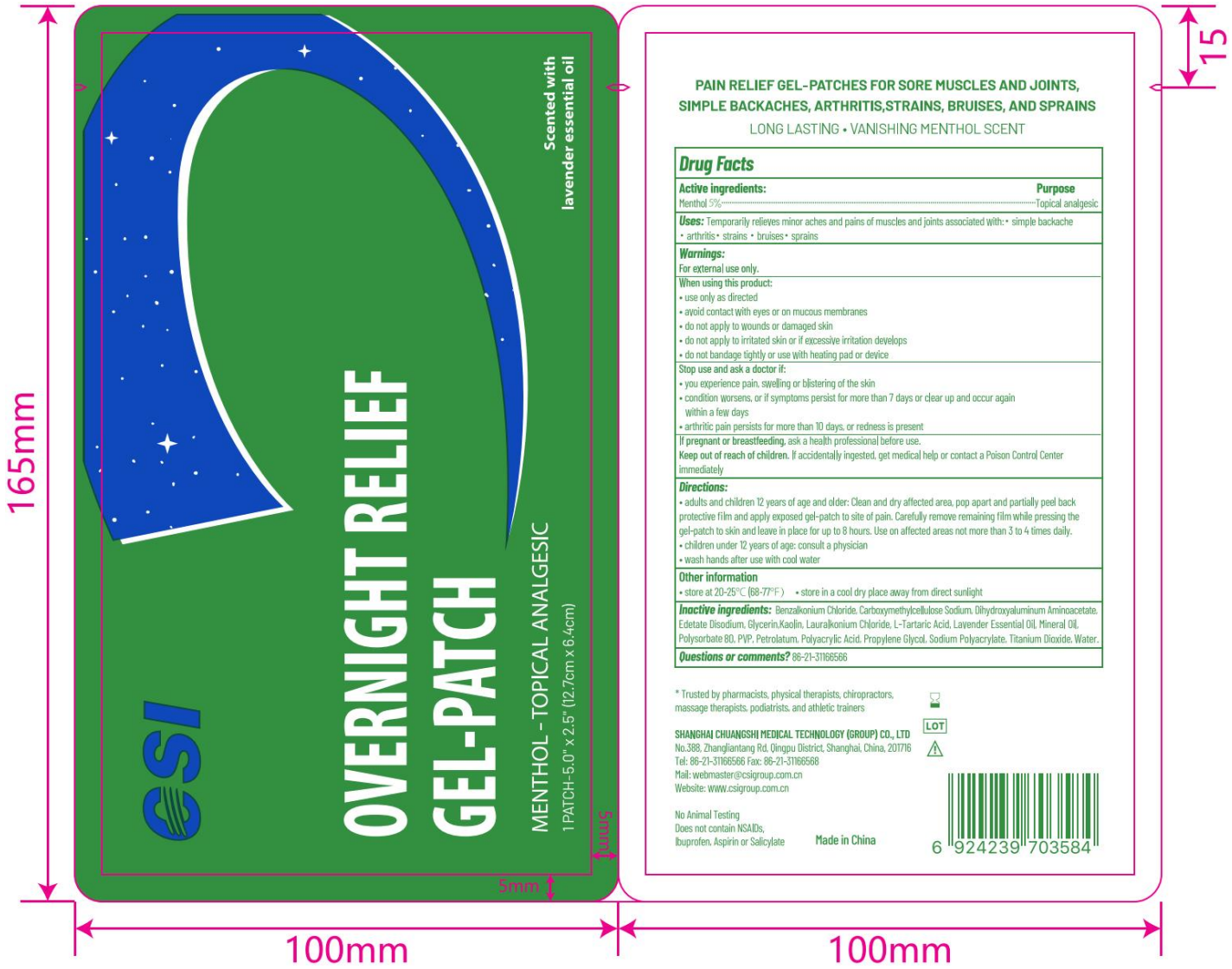
Questions or comments

Questions or comments: 86-21-31166566

Other information

- store at 20-25℃ (68-77℉)
- store in a cool dry place away from direct sunlight

Package label. Principal display panel



PAIN RELIEF GEL-PATCHES FOR SORE MUSCLES AND JOINTS, SIMPLE BACKACHES, ARTHRITIS,STRAINS, BRUISES, AND SPRAINS

LONG LASTING • VANISHING MENTHOL SCENT

Drug Facts

Active ingredients: **Purpose**
Menthol 5% ..... Topical analgesic

Uses: Temporarily relieves minor aches and pains of muscles and joints associated with: • simple backache • arthritis • strains • bruises • sprains

Warnings:

For external use only.

When using this product:
- use only as directed
- avoid contact with eyes or on mucous membranes
- do not apply to wounds or damaged skin
- do not apply to irritated skin or if excessive irritation develops
- do not bandage tightly or use with heating pad or device

Stop use and ask a doctor if:
- you experience pain, swelling or blistering of the skin
- condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days
- arthritic pain persists for more than 10 days, or redness is present

If **pregnant or breastfeeding,** ask a health professional before use.

Keep out of reach of children. If accidentally ingested, get medical help or contact a Poison Control Center immediately

Directions:
- adults and children 12 years of age and older: Clean and dry affected area, pop apart and partially peel back protective film and apply exposed gel-patch to site of pain. Carefully remove remaining film while pressing the gel-patch to skin and leave in place for up to 8 hours. Use on affected areas not more than 3 to 4 times daily.
- children under 12 years of age: consult a physician
- wash hands after use with cool water

Other information
- store at 20-25℃ (68-77℉) • store in a cool dry place away from direct sunlight

Inactive ingredients: Benzalkonium Chloride, Carboxymethylcellulose Sodium, Dihydroxyaluminum Aminoacetate, Edetate Disodium, Glycerin,Kaolin, Lauralkonium Chloride, L-Tartaric Acid, Lavender Essential Oil, Mineral Oil, Polysorbate 80, PVP, Petrolatum, Polyacrylic Acid, Propylene Glycol, Sodium Polyacrylate, Titanium Dioxide, Water.

Questions or comments? 86-21-31166566

* Trusted by pharmacists, physical therapists, chiropractors, massage therapists, podiatrists, and athletic trainers

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No Animal Testing
Does not contain NSAIDs, Ibuprofen, Aspirin or Salicylate

Made in China

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OVERNIGHT RELIEF GEL-PATCH

menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73557-133
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.05 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
KAOLIN (UNII: 24H4NWX5CO)	0.001 g in 1 g
TARTARIC ACID (UNII: W4888I119H)	0.001 g in 1 g
WATER (UNII: 059QF0KO0R)	0.3095 g in 1 g
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	0.0015 g in 1 g
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.06 g in 1 g
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	0.2 g in 1 g
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	0.001 g in 1 g
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	0.05 g in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	0.001 g in 1 g
MINERAL OIL (UNII: T5L8T28FGP)	0.03 g in 1 g
PETROLATUM (UNII: 4T6H12BN9U)	0.002 g in 1 g
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	0.001 g in 1 g
LAURALKONIUM CHLORIDE (UNII: 07HUP5A29X)	0.001 g in 1 g
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	0.018 g in 1 g
GLYCERIN (UNII: PDC6A3C0OX)	0.24 g in 1 g
POVIDONE K90 (UNII: RDH86HJV5Z)	0.012 g in 1 g
LAVENDER OIL (UNII: ZBP1YXW0H8)	0.02 g in 1 g
EDETATE DISODIUM (UNII: 7FLD91C86K)	0.001 g in 1 g

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73557-133-05	5 in 1 BOX	12/30/2022	
1	NDC:73557-133-01	8 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	12/30/2022	

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(73557-133) , label(73557-133)

Revised: 4/2024

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