

PRO-SERO PAIN RELIEF- menthol, methyl salicylate patch
Tieh Leh Biotech Co., Ltd.

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.

Active ingredients

Drug Facts

Active ingredients

Purpose

Menthol 4%.....	Topical analgesic
Methyl Salicylate 1%.....	Topical analgesic

Uses

Temporarily relieves mild to moderate aches and pains of muscles and joints associated with:

- arthritis
- simple backache
- sprains
- strains
- bruises

Warnings

For external use only

Allergy alert

If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

Do not use

- on the face or rashes
- on wounds or damaged skin
- if allergic to any ingredient of this product
- on a child under 12 years of age with arthritis-like conditions

Ask a doctor before use if

- you are allergic to topical products

When using this product

- wash hands after applying or removing patch
- avoid contact with eyes. If eye contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if

- rash, itching or skin irritation develops
- condition worsens
- symptoms last 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. Package not child resistant.

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

Directions

Adults and children 12 years of age and over:

- clean and dry affected area
- remove patch from film and apply to affected area
- leave in place for up to 8 to 12 hours
- apply a new patch up to 3 times daily
- **Children under 12 years of age:** Consult a doctor

Other information

- store at 68-77 degrees Fahrenheit (20-25 Celsius)
- avoid storing product in direct sunlight
- protect product from excessive moisture
- reseal unused patches in their pouch
- for some individuals, pain relief begins several hours after applying the patch

Inactive ingredients

Clematis Chinensis Root, FD&C Yellow No. 5, Frankincense, Indigotindisulfonate Sodium, Momordica Cochinchinensis Seed, Myrrh, Pinus Massoniana Resin, Ricinus Communis Seed, Sesame Oil, Yellow Wax, Zinc Oxide

Questions or comments?

Visit www.pro-sero.com

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- leave in place for up to 8 to 12 hours
- apply a new patch up to 3 times daily
- **Children under 12 years of age:** Consult a doctor

Other information

- store at 20 - 25 degrees Celsius (68-77 degrees Fahrenheit)
- avoid storing product in direct sunlight
- protect product from excessive moisture
- reseal unused patches in their pouch
- for some individuals, pain relief begins several hours after applying the patch

Inactive ingredients

Clematis Chinensis Root, FD&C Yellow No. 5, Frankincense, Indigotindisulfonate Sodium, Momordica Cochinchinensis Seed, Myrrh, Ricinus Communis Seed, Rosin, Sesame Oil, Yellow Wax, Zinc Oxide

Questions or comments?

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Principal Display Panel



Herbal Formula

Penetrating pain relief

Medicine for External Use

Quantity : 40
6.3in x 3.5in
(16cm x 9cm)

PRO-SERO PAIN RELIEF

menthol, methyl salicylate patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80846-100
Route of Administration	TOPICAL, TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	24 mg
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	96 mg

Inactive Ingredients

Ingredient Name	Strength
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SESAME OIL (UNII: QX10HYY4QV)	
CLEMATIS CHINENSIS ROOT (UNII: 8Z18N528CU)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
INDIGOTINDISULFONATE SODIUM (UNII: D3741U8K7L)	
MYRRH (UNII: JC71GJ1F3L)	
RICINUS COMMUNIS SEED (UNII: 7EK4SFN1TX)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
MOMORDICA COCHINCHINENSIS SEED (UNII: 2T87O1UPVD)	
PINUS MASSONIANA RESIN (UNII: 64S07U83T7)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80846-100-40	8 in 1 BOX	10/12/2020	
1		5 in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/01/2020	

Labeler - Tieh Leh Biotech Co., Ltd. (656113256)

Establishment

Name	Address	ID/FEI	Business Operations
Tieh Leh Biotech Co., Ltd.		656113256	manufacture(80846-100)

Revised: 9/2020

Tieh Leh Biotech Co., Ltd.