

**COOL PAP CATAPLASMA- methyl salicylate, l-menthol, dl-camphor, mentha oil, thymol gel  
Lydia 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.*

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**Drug Facts**

Methyl salicylate

l-Menthol

dl-Camphor

Mentha oil

Thymol

Kaolin

Zinc oxide

Titanium oxide

Gelatin

Glycerin

Liquid paraffin

Carboxymethylcellulose sodium

Polybutene

Sodium polyacrylate

Butylated hydroxy toluene

Polysorbate 60

Methoxyethylene maleicanhydride copolymer

Citric acid hydrate

Natural rubber latex

Purified water

Nonwoven fabric

Polyester film

Topical Analgesic

Temporarily relieves minor pain associated with - muscular pain - joint pain - backache - bruise - sprain

keep out of reach of the children

Adults and children 12 years of age and over: apply to affected area not more than 3 to 4 times daily.

Children under 12 years of age: do not use, consult a doctor

For easy application: partially peel back protective film and apply exposed patch to the site of pain.

Carefully remove remaining film while pressing patch to skin for secure adhesion.

use only as directed

do not bandage tightly or use with a healing pad

avoid contact with the eyes and mucous membranes

do not apply to wounds or damaged skin

for external use only

Cool Pap



Composition

**Each Sheet (14cm×10cm) contains :**

MethylSalicylate	262.5mg
l-Menthol	175.0mg
dl-Camphor	122.5mg
MenthaOil	87.5mg (26.3mg as Menthol)
Thymol	17.5mg

Dosage & Indication

1~2 times a day.  
Sprain, Bruise, Myalgia,  
Arthralgia, Shoulder pain etc.

Packing unit

5 sheets / Pack

## COOL PAP CATAPLASMA

methyl salicylate, l-menthol, dl-camphor, mentha oil, thymol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72988-0006
<b>Route of Administration</b>	TRANSDERMAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>THYMOL</b> (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	17.5 mg in 17.5 g
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH) (PEPPERMINT - UNII:V95R5KMY2B)	PEPPERMINT OIL	87.5 mg in 17.5 g
<b>LEVOMENTHOL</b> (UNII: BZ1R15MTK7) (LEVOMENTHOL - UNII:BZ1R15MTK7)	LEVOMENTHOL	17.5 mg in 17.5 g
<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	122.5 mg in 17.5 g
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	262.5 mg in 17.5 g

### Inactive Ingredients

Ingredient Name	Strength
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72988-0006-1	17.5 g in 1 PATCH; Type 0: Not a Combination Product	03/29/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part348	03/23/2019	

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**Labeler** - Lydia Co., Ltd. (695735569)

**Registrant** - Lydia Co., Ltd. (695735569)

**Establishment**

Name	Address	ID/FEI	Business Operations
Jeil Health Science Inc.		689851513	manufacture(72988-0006)

**Establishment**

Name	Address	ID/FEI	Business Operations
Lydia Co., Ltd.		695735569	label(72988-0006)

Revised: 3/2019

Lydia Co., Ltd.