

**LABOFLEX COOL AND HOT MENTHOL 1.25 PERCENT CAPSAICIN 0.025 PERCENT- menthol, capsaicin patch**  
**WOOSHIN LABOTTACH 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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**LaboFlex Cool & Hot Patch**

**ACTIVE INGREDIENTS**

Menthol 1.25%

Capsicum extract 0.025% as Capsaicin

**INACTIVE INGREDIENTS**

Aluminum Glycinate, Butylhydroxytoluene(BHT), Carboxymethylcellulose Sodium, Glycerin, Disodium EDTA, Kaolin, Polysorbate 80, Povidone-K90, Propylene Glycol, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide, Purified Water

**PURPOSE**

Topical Analgesic

**WARNINGS**

**For external use only**

Do not use ■ On wounds or damaged skin ■ With a heating pad ■ If you are allergic to any ingredients of this product.

**Keep out of reach of children**

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

**Uses**

For temporary relief of minor aches and pains of muscles and joints associated with ■ Simple backache ■ Arthritis ■ Strains ■ Bruises ■ Sprains

**Directions**

**Adult and children 12 years of age and over :**

■ Clean and dry affected area ■ Remove film from patch and apply to the skin ■ Apply 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

### **Other Information**

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

### **Questions or Comments**

Questions or comments? Call toll-free 1-800-655-0252 or email: [wooshinlabo-us@wooshinmed.com](mailto:wooshinlabo-us@wooshinmed.com)

### **When using this product**

When using this product ■ Use only as directed ■ Avoid contact with the eyes, mucous membranes or rashes ■ Do not bandage tightly ■ Discontinue use at least 1 hour before a bath or shower ■ Do not use immediately after a bath or shower.

### **Stop use and ask a doctor if**






**Stop use and ask a doctor if** ■ Skin reactions such as redness, itching, rash excessive irritation, burning sensation, swelling or blistering occur ■ Condition worsen ■ Symptoms persist for more than 7 days ■

Symptoms clear up and occur again within a few days.


### **If pregnant or breast-feeding**

**If pregnant or breast-feeding**, ask a health professional before use.


### **PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**


Drug Facts	
<b>Active ingredient</b>	<b>Purpose</b>
Capsicum extract 0.025% as Capsaicin	Topical Analgesic
L-Menthol 1.25%	Topical Analgesic
<b>Uses</b> For temporary relief of minor aches and pains of muscles and joints associated with ■ Simple backache ■ Arthritis ■ Strains ■ Bruises ■ Sprains	
<b>Warnings</b> <b>For external use only</b> <b>Do not use</b> ■ On wounds or damaged skin ■ With a heating pad ■ If you are allergic to any ingredients of this product. <b>When using this product</b> ■ Use only as directed ■ Avoid contact with the eyes, mucous membranes or rashes ■ Do not bandage tightly ■ Discontinue use at least 1 hour before a bath or shower ■ Do not use immediately after a bath or shower. <b>Stop use and ask a doctor if</b> ■ Skin reactions such as redness, itching, rash excessive irritation, burning sensation, swelling or blistering occur ■ Condition worsens ■ Symptoms persist for more than 7 days ■ Symptoms clear up and occur again within a few days. <b>If pregnant or breast-feeding</b> , ask a health professional before use. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away. <b>Directions</b> <b>Adults and children 12 years of age and over</b> ■ Clean and dry affected area ■ Remove film from patch and apply to the skin ■ Apply to affected area not more than 3 to 4 times daily ■ Remove patch from the skin after at most 8-hour application. <b>Children under 12 years of age</b> Consult a doctor. <b>Other information</b> ■ Avoid storing product in direct sunlight ■ Protect product from excessive moisture <b>Inactive ingredients</b> Aluminum Glycinate, Butylhydroxytoluene(BHT), Carboxymethylcellulose Sodium, Glycerin, Disodium EDTA, Kaolin, Polysorbate 80, Povidone-K90, Propylene Glycol, Sodium Polycrylate, Tartaric Acid, Titanium Dioxide, Purified Water <b>Questions or comments?</b> Call toll-free 1-800-655-0252 or email: wooshinlabo-us@wooshinmed.com	



**WOOSHIN LABOTTACH**  
 Manufactured for  
 Wooshin Labottach Co., Ltd. USA  
 2030 Main Street, Suite 100  
 Irvine CA 92614  
 Made in Slovenia



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**LaboFlex™**

**Maximum Strength**

NDC 82957-103-11



**For minor aches and pain relief**

- Back
- Neck
- Shoulders
- Knees & Elbows

**LaboFlex™**

**COOL & HOT**

**LaboFlex™**

**Topical Analgesic**






- Simple Back Aches, Arthritis, Strains, Bruises & Sprains
- Easy to apply
- Lasts up to 8 hours
- Resealable pouch




**Pain Relieving Hydrogel Patch**  
 Capsaicin 0.025%  
 Menthol 1.25%

**5 Patches** 3.9" x 5.5" (10cm x 14cm)


**LaboFlex™**


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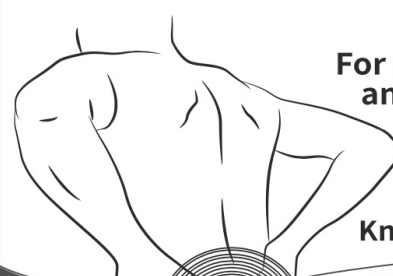
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**LaboFlex™**

**Maximum Strength**

NDC 82957-103-12



**For minor aches and pain relief**

- Back
- Neck
- Shoulders
- Knees & Elbows


**LaboFlex™**

**COOL & HOT**

**LaboFlex™**

**Topical Analgesic**

Capsaicin 0.025%  
 Menthol 1.25%



**Pain Relieving Hydrogel Patch**

**5 Patches** 3.9" x 5.5" (10cm x 14cm)

**LaboFlex™**

# LABOFLEX COOL AND HOT MENTHOL 1.25 PERCENT CAPSAICIN 0.025 PERCENT

menthol, capsaicin patch

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82957-103
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	87.5 mg
<b>CAPSAICIN</b> (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	1.75 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>DIHYDROXYALUMINUM AMINOACETATE</b> (UNII: DO250MG0W6)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>POVIDONE K90</b> (UNII: RDH86HJV5Z)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>SODIUM POLYACRYLATE (2500000 MW)</b> (UNII: 05I15JN12J)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TARTARIC ACID</b> (UNII: W4888I119H)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:82957-103-11	2 in 1 CARTON	02/20/2023	
1		5 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:82957-103-12	5 in 1 POUCH; Type 0: Not a Combination Product	02/20/2023	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part348	02/20/2023	

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**Labeler** - WOOSHIN LABOTTACH CO., LTD. (688269808)

**Registrant** - WOOSHIN LABOTTACH CO., LTD. (688269808)

**Establishment**

Name	Address	ID/FEI	Business Operations
WOOSHIN LAPACHE d.o.o.		507385209	manufacture(82957-103)

Revised: 3/2023

WOOSHIN LABOTTACH CO., LTD.