

LABOFLEX COOL AND HOT MENTHOL 1.25 PERCENT CAPSAICIN 0.025 PERCENT- menthol, capsaicin patch
Laboflex, Inc.

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.

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

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	
Active ingredient	Purpose
Capsicum extract 0.025% as Capsaicin	Topical Analgesic
L-Menthol 1.25%	Topical Analgesic
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Inactive ingredients	
Butylhydroxytoluene, Carboxymethylcellulose sodium, Dihydroxyaluminum aminoacetate, Edetate sodium, Glycerin, Kaolin, Polysorbate 80, Polyvinylpyrrolidone, Propylene glycol, Sodium polyacrylate, Tartaric acid, Titanium dioxide, Water	
Questions or comments? Call toll-free 1-800-655-0252 or email: wooshinlabo-us@wooshinmed.com	

LABO FLEX
 Manufactured for Laboflex INC.
 46 Corporate Park, Suite 140
 Irvine CA 92606
 Made in Slovenia



NDC 83655-102-15

LaboFlex™

Maximum Strength

For minor aches and pain relief

- Back
- Neck
- Shoulders
- Knees & Elbows



LaboFlex™

COOL & HOT

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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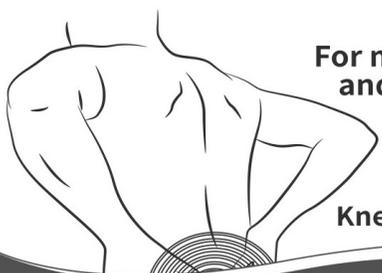
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- Neck
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Pain Relieving Hydrogel Patch

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

20mm

LABOFLEX COOL AND HOT MENTHOL 1.25 PERCENT CAPSAICIN 0.025 PERCENT

menthol, capsaicin patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83655-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TARTARIC ACID (UNII: W4888I119H)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
KAOLIN (UNII: 24H4NWX5CO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83655-103-11	2 in 1 CARTON	08/28/2023	
1		5 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:83655-103-12	5 in 1 POUCH; Type 0: Not a Combination Product	08/28/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/28/2023	

Labeler - Laboflex, Inc. (128394050)

Registrant - Laboflex, Inc. (128394050)

Establishment

Name	Address	ID/FEI	Business Operations
WOOSHIN LAPACHE d.o.o.		507385209	manufacture(83655-103)

Revised: 9/2023

Laboflex, Inc.