

FLEX24 PERFORMANCE PEN- camphor liquid

Larasan Pharmaceutical Corporation

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 Ingredient

Camphor, 7.79%

Purpose

Topical analgesic

Uses

For temporary relief of minor aches and pains of muscle and joints associated with simple arthritis, strains, bruises and sprains

Warnings

For external use only

Do not

apply to open wounds, or damaged, broken, or irritated skin

Stop use and ask a doctor

if condition worsens or if there is redness or irritation in the applied area or if symptoms persist for more than 7 days or clear up and occur again within a few days

Caution

- Discontinue use if excessive irritation of the skin develops
- Avoid contact with the eyes and mucous membranes
- Arthritis: If pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age consult a physician immediately

Pregnant or breast feeding

ask healthcare professional about use

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

Adults and children over the age of 12:

- Remove plastic top from device and put aside till after treatment
- Apply ointment to affected area
- Repeat if necessary but no more than 3 treatments a day.

Children under 12, consult a doctor before use.

Inactive Ingredients

Aconitum kusnezoffii root, Angelica dahurica root, Angelica sinensis root, Asarum heterotropoides var. mandshuricum root, Drynaria fortunei root, Eleutherococcus nodiflorus root bark, Ethyl alcohol, Eucalyptus oil, Frosythia suspensa fruit, Frankincense, Gardenia jasminoides fruit, Lavender oil, Lemon, Myrrh, Paeonia suffruticosa root bark, Peppermint oil, Pinellia ternata root, Red paeonia lactiflora root, Rhemannia glutinosa root (raw), Rhubarb, Safflower, Tangerine peel, Turmeric, White paeonia lactiflora root, Wintergreen oil, Zanthoxylum nitidum root, Zeodary

Other Information

Keep sealed in a dry environment at no more than 85°F/29°C and avoid any direct sun exposure

Questions/Comments?

www.larasan.com/performancepen

Distributed By:

Larasan Pharmaceutical Corporation

401 East Las Olas Blvd., Suite 1400

Ft. Lauderdale, FL 33301

Tel. 1-855-LARASAN

NDC 54641-004-02

Made in China

Flex24™ Performance Pen

Topical Analgesic

Aches Pains Bruises Sprains

0.34 fl. oz. (10 mL)





FLEX24™

PERFORMANCE PEN

TOPICAL ANALGESIC

Drug Facts

Active Ingredient
Camphor, 7.79%Topical Analgesic

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Pregnant or breast feeding ask healthcare professional about use.
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 ■ Remove plastic top from device and put aside till after treatment
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Lot No.
Expiry Date:


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FLEX24 PERFORMANCE PEN

camphor liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54641-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	7.79 g in 100 mL
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Inactive Ingredients

Ingredient Name	Strength
ANGELICA DAHURICA ROOT (UNII: 1V63N2S972)	
ACONITUM KUSNEZOFFII ROOT (UNII: 3L29I4K8KX)	
ANGELICA SINENSIS ROOT (UNII: B66F4574UG)	
ASARUM HETEROTROPOIDES VAR. MANDSHURICUM ROOT (UNII: HK49KSK8L3)	
DRYNARIA FORTUNEI ROOT (UNII: 731W842X8Q)	
ELEUTHEROCCUS NODIFLORUS ROOT BARK (UNII: W7PRK433YB)	
ALCOHOL (UNII: 3K9958V90M)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
FORSYTHIA SUSPensa FRUIT (UNII: P4793M1ES5)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
GARDENIA JASMINOIDES FRUIT (UNII: 7CTH8MD549)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
LEMON (UNII: 24RS0A988O)	
MYRRH (UNII: JC71GJ1F3L)	
PAEONIA SUFFRUTICOSA ROOT BARK (UNII: BUG255FE7X)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
PINELLIA TERNATA ROOT (UNII: G9AET085M5)	
PAEONIA LACTIFLORA ROOT (UNII: 3Z3866YW6P)	
REHMANNIA GLUTINOSA ROOT (UNII: 1BEM3U6LQQ)	
RHUBARB (UNII: G280W4MW6E)	
SAFFLOWER (UNII: 4VBL71TY4Y)	
TANGERINE PEEL (UNII: JU3D414057)	
TURMERIC (UNII: 856YO1Z64F)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
ZANTHOXYLUM NITIDUM ROOT (UNII: L2CQZ81759)	
ZEDOARY (UNII: 123C43G128)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54641-004-02	10 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	04/08/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/08/2014	

Labeler - Larasan Pharmaceutical Corporation (078350375)

Establishment

Name	Address	ID/FEI	Business Operations
Dong E E Hua Medical Technology Co Ltd		5278 13247	manufacture(54641-004)

Revised: 12/2019

Larasan Pharmaceutical Corporation