FLEX24 PAIN PEN- camphor liquid Laras an 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, cramps, bruises, and sprains

Warnings

IFor 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.

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 liniment to affected area
- Repeat as necessary but no more than 3 treatments per day
- Children under 12, consult a doctor before use.

Other Information

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

Inactive Ingredients

Aconitum Kusnezoffii Root, Angelica Dahurica Root, Angelica Sinesis Root, Asarum Heterotropoides var. 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, Rehmannia Glutinosa Root (Raw), Rhubarb, Safflower, Tangerine Peel, Turmeric, White Paeonia Lactiflora Root, Wintergreen Oil, Zanthoxylum Nitidum Root, Zeodary

Questions/Comments?

www.larasan.com/painpen

Flex24TM Pain Pen

Powerful Pain Relief

Distributed by: Larasan Pharmaceutical Corporation, 401 East Las Olas Blvd., Suite 1400, Ft. Lauderdale, FL 33301

Tel. 1-855-LARASAN

NDC 54641-003-02

Made in Chinda

Lot No.:

Expiry Date:

Larasan

Nature Bioscience Health

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Flex24TM Pain Pen

Powerful Pain Relief Aches Pains Bruises Sprains Topical Analgesic 0.61 fl. oz. (18 mL)





Drug Facts

POWERFUL PAIN RELIEF

Active Ingredient Purpose Camphor, 7.79%. Topical Analgesic

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Peppermint Oil, Pinellia Ternata Root, Red Paeonia Lactiflora Root,
Rehmannia Glutinosa Root (Raw), Rhubarb, Safflower,
Tangerine Peel, Turmeric, White Paeonia Lactiflora Root, Wintergreen
Oil, Zanthoxylum Nitidum Root, Zeodary

Questions/Comments? www.larasan.com/painpen

Expiry Date:

Distributed by:

Larasan Pharmaceutical Corporation 401 East Las Olas Blvd., Suite 1400 Ft. Lauderdale, FL 33301 Tel. 1-855-LARASAN

Lerasan

FLEX24 PAIN PEN

camphor liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:54641-003

Route of Administration TOPICAL

Active Ingradient/Active Mojety

| Active ingredient/Active wrotety | | | | | |
|--|----------------------|------------------|--|--|--|
| Ingredient Name | Basis of Strength | Strength | | | |
| CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941) | CAMPHOR (NATURAL) | 7.79 g in 100 mL | | | |

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| ACONITUM KUSNEZOFFII ROOT (UNII: 3L2914K8KX) | |
| ANGELICA DAHURICA ROOT (UNII: 1V63N2S972) | |
| ANGELICA SINENSIS ROOT (UNII: B66F4574UG) | |
| DRYNARIA FORTUNEI ROOT (UNII: 731W842X8Q) | |
| ELEUTHEROCOCCUS NODIFLORUS ROOT BARK (UNII: W7PRK433YB) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| EUCALYPTUS OIL (UNII: 2R04ONI662) | |
| FORSYTHIA SUSPENSA FRUIT (UNII: P4793M1ES5) | |
| FRANKINCENSE (UNII: R9 XLF1R1WM) | |
| GARDENIA JASMINO IDES FRUIT (UNII: 7CTH8 MD549) | |
| LAVENDER O IL (UNII: ZBP1YXW0H8) | |
| LEMON (UNII: 24RS0A988O) | |
| MYRRH (UNII: JC71GJ1F3L) | |
| PAEONIA SUFFRUTICO SA ROOT BARK (UNII: BUG255FE7X) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |
| PINELLIA TERNATA ROOT (UNII: G9 AET0 85M5) | |
| PAEONIA LACTIFLORA ROOT (UNII: 3Z3866YW6P) | |
| REHMANNIA GLUTINOSA ROOT (UNII: 1BEM3U6LQQ) | |
| RHUBARB (UNII: G280W4MW6E) | |
| SAFFLOWER (UNII: 4VBL71TY4Y) | |
| TANGERINE PEEL (UNII: JU3D414057) | |
| TURMERIC (UNII: 856 YO 1Z64F) | |
| METHYL SALICYLATE (UNII: LAV5U5022Y) | |
| ZANTHO XYLUM NITIDUM ROOT (UNII: L2CQZ81759) | |
| ZEDO ARY (UNII: 123C43G128) | |

| Packaging | | | | |
|------------------------|---|-------------------------|-----------------------|--|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 NDC:54641-003- 02 | 18 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product | 0 2/10/20 15 | | |

| Marketing Information | | | | |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part348 | 02/10/2015 | | |
| | | | | |

Labeler - Larasan Pharmaceutical Corporation (078350375)

| Establishment | | | | | |
|--|---------|-----------|-------------------------|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| Dong E E Hua Medical Technology Co Ltd | | 527813247 | manufacture (54641-003) | | |