LUROSIL- menthol gel Pacific Health Collabroative

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.

Drug Facts

Active ingredient

Menthol 2.5%

Uses

temporarily relieves the minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

For external use only

Do not use

- on wound s or damaged skin
- with a heating pad
- on a child under 12 years of age with arthritis-like conditions

Ask a doctor before use if you have

redness over the affected area.

When using this product

- avoid contact with eyes or mucous membranes
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- excessive skin irritation occurs

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- adults and children 12 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: ask a doctor

Other information

• store at 20° to 25°C (68° to 77°F)

Inactive ingredients

camphor, carbomer 940, glycerin, isoprophyl alcohol, methylparaben, polysorbate 60, purified water, and trolamine

Package label



Contact Us

Purpose

Topical analgesic

LUROSIL

menthol gel

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58697-539 |
|--------------|----------------|--------------------|---------------|
|--------------|----------------|--------------------|---------------|

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| Menthol (UNII: L7T10 EIP3A) (Menthol - UNII:L7T10 EIP3A) | Menthol | 2.5 g in 100 g |

Inactive Ingredients

trolamine (UNII: 9O3K93S3TK)

| macuve ingreaters | | |
|--|----------|--|
| Ingredient Name | Strength | |
| CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) | | |
| CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E) | | |
| glycerin (UNII: PDC6A3C0OX) | | |
| isopropyl alcohol (UNII: ND2M416302) | | |
| methylparaben (UNII: A218 C7H19 T) | | |
| polysorbate 60 (UNII: CAL22UVI4M) | | |
| water (UNII: 059QF0KO0R) | | |

Packaging

| | - | | | | |
|---|------------------|---------------------|----------------------|--------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:58697-539-02 | 1 in 1 BOX | | | |
| 1 | | 57 g in 1 TUBE | | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 06/17/2013 | |

$\pmb{Labeler} \textbf{ -} \textbf{ Pacific Health Collaboroative (555568133)}$

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