

FLEXIN- menthol and capsaicin patch

Whyteman Labs LLC

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 :

Menthol 5.00%

External Analgesic/Counterirritant

Capsaicin 0.0375%

External Analgesic

USES :

Use for the temporary relief of minor aches and muscle pains associated with arthritis, simple backache, strains, sprains, muscle soreness and stiffness.

WARNINGS :

- **For external use only.** Use only as directed. Avoid contact with eyes and mucous membranes.
- Do not cover with bandage.
- Do not use on wounds or damaged skin.
- **Keep out of reach of children.** Consult physician for use in children under 12.
- Do not use if you are allergic to Menthol or Capsaicin.
- Stop use and ask a doctor if conditions worsen, symptoms persist for more than 7 days or clear up and occurs again within a few days, or if rash, itching or excessive skin irritation occurs.

DIRECTIONS :

- Adults and children 12 years and over apply to affected area; change patch 2 to 3 times daily.
- Children under 12 years, consult a physician before use.
- How to apply:
- Clean and dry affected area.
- Cut open pouch and remove patch. Remove protective film and apply directly to area of pain.
- Apply to affected area not more than 3 times daily.
- Wash hands with soap after applying patch.
- Reseal pouch containing unused patches.

INACTIVE INGREDIENTS :

Water, Glycerine, Sodium Polyacrylate, Polysorbate 80,

Aloe Barbadesis Leaf (Aloe Vera Gel) Juice, EDTA Disodium salt,

Diazolidinyl Urea, Methylparaben, Iodopropynyl Butylcarbamate, Propylparaben.

Store below 25°C (77°F)

Avoid direct sunlight.

PRINCIPAL DISPLAY PANEL

Flexin

DRUG FACTS :

ACTIVE INGREDIENTS :

| | | |
|-----------|---------|------------------------------------|
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| Capsaicin | 0.0375% | External Analgesic |

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Manufactured in China for : Whyteman Labs LLC
4115 West Spruce Street, Tampa, FL 33607
Tel : 1-800-430-1678



Lot : 150
Expiry d

Whyteman Labs

Flexin

QTY 15 PATCHES
5 Envelopes containing 5 patches each

NDC: 69695-1974-1

Flexin

FLEXIN

menthol and capsaicin patch

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69695-1974 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM) | CAPSAICIN | 0.000375 |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 0.05 |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| EDETIC ACID (UNII: 9G34HU7RV0) | |
| WATER (UNII: 059QF0KO0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:69695-1974-1 | 15 in 1 BOX | | |
| 1 | | 5 in 1 POUCH; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 07/13/2015 | |

Labeler - Whyteman Labs LLC (079758831)

Revised: 11/2015

Whyteman Labs LLC