# PAIN GOODBYE AQUEOUS PATCH- methyl salicylate patch Austin Biotechnology 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.

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#### PAIN GOODBYE AQUEOUS BALM PATCH

#### **ACTIVE INGREDIENTS**

Methyl Salicylate 50 mg

L-Methenol 80 mg

#### **PURPOSE**

Methyl Salucylate External Analgesic L-Methenol External Analgesic

#### **USES**

Uses for the temporary relief of minor aches, and points of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains.

#### **WARNINGS**

For External Use Only. Do not use on wounds, on infected or damaged skin.

#### Stop use and ask a doctor if

Keep out of reach of children to avoid accidental poisoning. If swallowed, get medical help or consult a poison control center right away.

#### Stop use and ask a doctor if

Condition worsens.

Symptom clears up and occurs again within a few days.

Symptom persists for more than 7 days.

Nausea, vomitting, abdominal discomfort, diarrhea, or skin rash occurs.

Excessive irritation of the skin develops.

#### Stop use and ask a doctor if

Avoid contact with eyes or mucous membranes.

Do not bandage tightly.

When using for pain of arthritis:

In conditions affecting children under 12 years of age

If red nose is present

If pain persists for more than 10 days

#### WARNINGS

For children under 12 years of age, do not use, consult a doctor.

#### **Directions**

Adult and children 12 years of age and older; Remove the clear film backing and apply to the sore area of skin. Use not than 3 times daily.

Bandage will remain effective after 24 hours and will be even more effective when using after a bath.

Do not apply to extremely hairy skin. Highly adhesive bandage may hurt skin upon removal.

Other Information:

Keep container tightly closed. Once opened, fold the opening and keep pressed. Close with a clip. Store at room temperature.

#### INACTIVE INGREDIENTS

Gelatin, Myrrhm, Sesame Oil, Water and Zinc Oxide



methyl salicylate patch

| Product  | Inform | ation |
|----------|--------|-------|
| PIOCHICI |        | alion |

Product Type HUMAN OTC DRUG Item Code (Source) NDC:15667-7396

Route of Administration TOPICAL

| Active Ingredient/Active Moiety  |                             |                     |  |
|--|-----------------------------|---------------------|--|
| Ingredient Name  | Basis of Strength           | Strength            |  |
| METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)                          | METHYL SALICYLATE           | 50 mg<br>in 1000 mg |  |
| <b>2-(L-MENTHO XY) ETHANO L</b> (UNII: 5ZWW23169 H) (2-(L-MENTHO XY)ETHANO L - UNII:5ZWW23169 H) | 2-(L-<br>MENTHO XY)ETHANO L | 80 mg<br>in 1000 mg |  |

| Inactive Ingredients            |          |
|---------------------------------|----------|
| Ingredient Name                 | Strength |
| GELATIN (UNII: 2G86QN327L)      |          |
| MYRRH (UNII: JC71GJ1F3L)        |          |
| SESAME O IL (UNII: QX10 HYY4QV) |          |
| WATER (UNII: 059QF0KO0R)        |          |
| ZINC OXIDE (UNII: SOI2LOH54Z)   |          |

| F | Packaging        |                     |                      |                    |
|---|------------------|---------------------|----------------------|--------------------|
| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:15667-7396-5 | 5 in 1 BAG          |                      |                    |
| 1 | NDC:15667-7396-3 | 1000 mg in 1 BAG    |                      |                    |

| Marketing Information   |  |                      |                    |
|-------------------------|--|----------------------|--------------------|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part348                                  | 10/26/2011           |                    |
|                         |  |                      |                    |

## Labeler - Austin Biotechnology Inc (656001949)

### **Registrant** - Austin Biotechnology Inc (656001949)

| Establishment            |         |           |                         |
|--------------------------|---------|-----------|-------------------------|
| Name                     | Address | ID/FEI    | Business Operations     |
| Austin Biotechnology Inc |         | 656001949 | manufacture(15667-7396) |

Revised: 10/2013 Austin Biotechnology Inc