METHYL SALICYLATE- methyl salicylate patch
Alexso, 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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Methyl Salicylate Patch

Drug Facts

Active ingredient

Purpose
Methyl Salicylate 10% .................................................................Topical analgesic

Uses
For the temporary relief of minor aches and pains of muscles and joints, such as simple backache, lumbago, arthritis, neuralgia, strains, bruises, and sprains.

Warnings
For external use only. Use only as directed or as directed by a health care professional.
Read all warnings and directions before use.
Discontinue use at least one hour prior to bath, shower, or swimming; do not use immediately after bath, shower, or swimming.

Do not use:
• On wounds, cuts, damaged or infected skin
• On eyes, mouth, genitals, or any other mucous membranes

Keep out of reach of children.
Consult physician for children under 18.

When using this product
• Avoid contact with the eyes
• You may experience a burning sensation. The intensity of this reaction varies among individuals and may be severe. With regular use, this sensation generally disappears after several days.
Avoid contact with the eyes, lips, nose and mucous membranes
Do not tightly wrap or bandage the treated area
Do not apply heat to the treated area immediately before or after use

Stop use and ask a doctor if
- allergic reaction occurs
- condition worsens or does not improve within 7 days
- symptoms clear up and return within a few days
- redness, irritation, swelling, pain or other symptoms begin or increase

Directions

Adults and children 18 years of age and older:
Apply 1 patch to the affected area of intact skin up to 3 times a day. Do not leave patch on for more than 8 hours at a time.
- Clean and dry the affected area.
- Open pouch and remove one patch.
- Remove any protective film and apply directly to affected area of pain. Apply immediately after removal from the protective envelope.
- Wash hands with soap and water after handling the patches.
- Reseal pouch containing unused patches after each use. Do not store patch outside the sealed envelope.
- Fold used patches so that the adhesive side sticks to itself and safely discard used patches or pieces of cut patches where children and pets cannot get to them.

Children under 18 years: Ask a physician

Other information
- May be applied under occlusive dressing.
- Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F). See USP Controlled Room Temperature.

Inactive ingredients
Polysorbate 80, Glycerin, Sodium Cellulose Glycolate, Sodium Polyacrylate, Vitamin E, EDTA Disodium Salt, Kaolin, Water, Methylparaben

Methyl Salicylate 10% Patch
NDC: 50488-2010-1

10 Patches
Manufactured for:
Alexso, Inc
Los Angeles, CA 90064
METHYL SALICYLATE
methyl salicylate patch

Product Information

Product Type: HUMAN OTC DRUG
Route of Administration: TOPICAL
Item Code (Source): NDC:50488-2010

Active Ingredient/Active Moiety

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<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)</td>
<td>METHYL SALICYLATE</td>
<td>10 g in 100 g</td>
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Inactive Ingredients

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<th>Ingredient Name</th>
<th>Strength</th>
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<td>POLYSORBATE 80 (UNII: 6OZP39ZG8H)</td>
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<td>GLYCERIN (UNII: PDC6A3C00X)</td>
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CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)
ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
EDETATE DISODIUM (UNII: 7FLD91C86K)
KAOLIN (UNII: 24H4NWX5CO)
WATER (UNII: 059QF0KO0R)
METHYLPARABEN (UNII: A2I8C7HI9T)
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)

Packaging

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<th>Marketing End Date</th>
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<td>2 in 1 BOX</td>
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<td>1</td>
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<td>5 in 1 POUCH</td>
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Marketing Information

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Labeler - Alexso, Inc (963338061)

Revised: 2/2021