

**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**

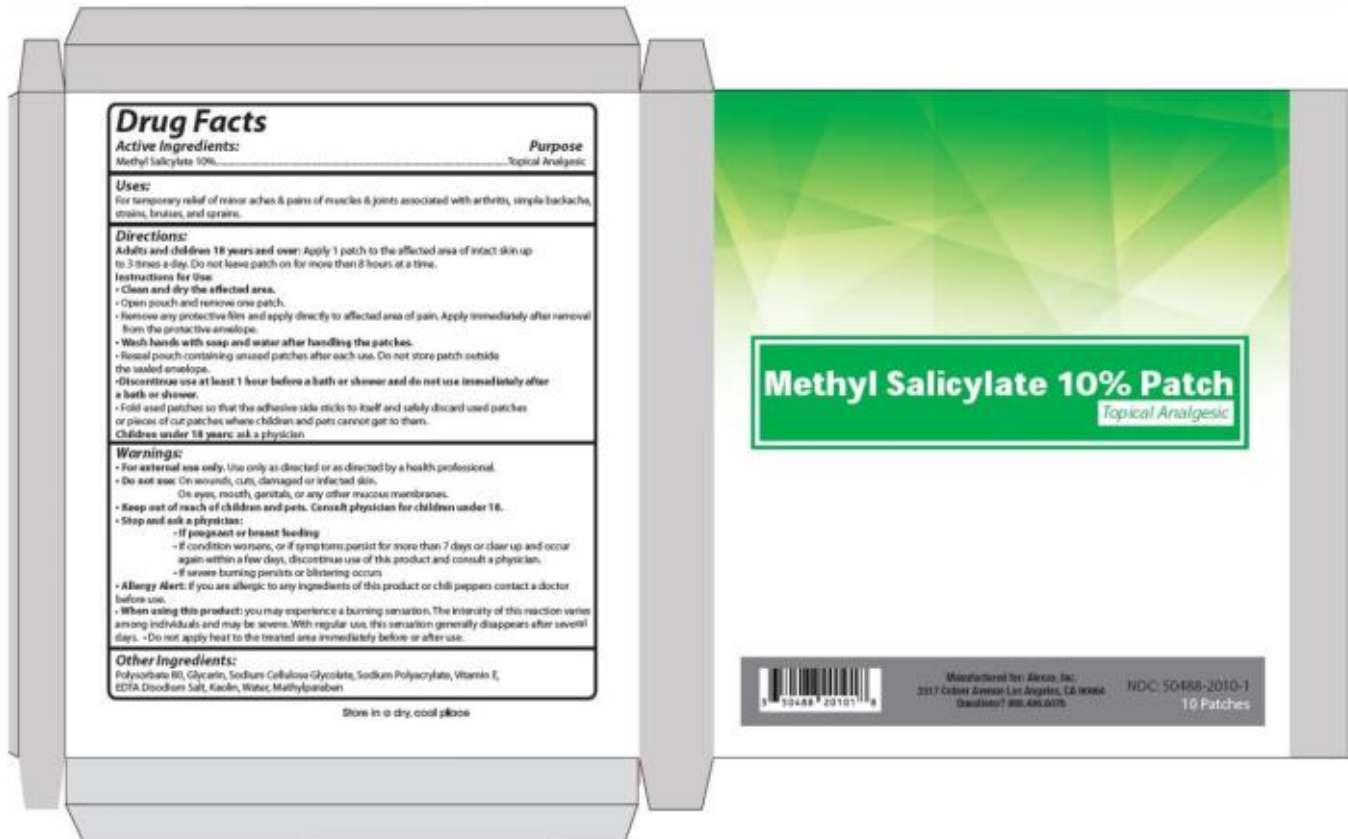
NDC: 50488-2010-1

**10 Patches**

Manufactured for:  
Alexso, Inc  
Los Angeles, CA 90064

# PRINCIPAL DISPLAY PANEL

Methyl Salicylate 10% Patch  
 Topical Analgesic  
 NDC 50488-2010-1  
 10 Patches



## METHYL SALICYLATE

methyl salicylate patch

### Product Information

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	10 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>SODIUM POLYACRYLATE (8000 MW)</b> (UNII: 285CYO341L)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50488-2010-1	2 in 1 BOX	02/11/2021	
1		5 in 1 POUCH		
1		100 g in 1 PATCH; 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	02/11/2021	

**Labeler** - Alexso, Inc (963338061)

Revised: 2/2021

Alexso, Inc