# **METHYL SALICYLATE-** methyl salicylate patch Alexso, Inc

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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



### **METHYL SALICYLATE**

methyl salicylate patch

**Route of Administration** 

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50488-2010	

**TOPICAL** 

### **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) METHYL SALICYLATE 10 g in 100 g

Inactive Ingredients			
Ingredient Name	Strength		
POLYSORBATE 80 (UNII: 60ZP39ZG8H)			
GLYCERIN (UNII: PDC6A3C0OX)			
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)			
.ALPHATOCOPHEROL (UNII: H4N855PNZ1)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			
KAOLIN (UNII: 24H4NWX5CO)			

WATER (UNII: 059QF0KO0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	

P	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 Drug	505G(a)(3)	02/11/2021			

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

Revised: 12/2024 Alexso, Inc