

METHYL SALICYLATE- methyl salicylate patch
Preferred Pharmaceuticals 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.

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:

Relabeled by: Preferred Pharmaceuticals Inc.

PRINCIPAL DISPLAY PANEL

Methyl Salicylate 10% Patch
Topical Analgesic
NDC 68788-8064
10 Patches

<div data-bbox="152 592 396 655"> <h1>Methyl Salicylate</h1> <h2>10% Patch</h2> <p>Brand Name</p> <p>Active Ingredient: Methyl Salicylate 10%...topical analgesic</p> <p>Pkg Size: Exp Date:</p> <p>Lot#:</p> <p>Batch#:</p> <p>Ins:</p> <p>Mfg: Alexso Inc.; Los Angeles, CA</p> <p>Prod#:</p> <p>Warning</p> <p>For external use only. Store in a dry, cool place at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) as USP Controlled Room Temperature. Do not use on wounds, cuts, damaged or infected skin. On eyes, mouth, genitals, or any other mucous membranes. See box for additional information and warnings.</p> </div>	<div data-bbox="482 581 688 617"> <p>PREFERRED</p> <p>Pharmaceuticals, Inc.</p> <p>Alhambra, CA 91801</p> </div>	<div data-bbox="745 592 1071 642"> <p>CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed</p> </div>	<div data-bbox="1114 588 1291 663"> <p>Methyl Salicylate 10% Patch</p> <p>Qty: Ins:</p> <p>Lot#: Bat#:</p> <p>Prod# (NDC):</p> </div>	<div data-bbox="1391 625 1412 653"> <p>Log</p> </div>
<div data-bbox="474 732 518 917"> </div>	<div data-bbox="531 739 617 1020"> <p>Directions English</p> <p>Use as directed by your doctor</p> </div>	<div data-bbox="758 676 808 747"> </div> <div data-bbox="829 751 915 1020"> <p>Instrucciones Español:</p> <p>Usó según lo dirigido por su doctor</p> </div>	<div data-bbox="1114 695 1291 756"> <p>Methyl Salicylate 10% Patch</p> <p>Qty: Ins:</p> <p>Lot#: Bat#:</p> <p>Prod# (NDC):</p> </div>	<div data-bbox="1391 728 1412 760"> <p>Chart</p> </div>
<div data-bbox="474 848 518 917"> </div>			<div data-bbox="1114 816 1291 877"> <p>Methyl Salicylate 10% Patch</p> <p>Qty: Ins:</p> <p>Insurance NDC:</p> <p>Lot#: Bat#:</p> </div>	<div data-bbox="1391 835 1412 882"> <p>Billing</p> </div>
			<div data-bbox="1114 924 1291 982"> <p>Methyl Salicylate 10% Patch</p> <p>Qty: Ins:</p> <p>Lot#: Bat#:</p> <p>Prod# (NDC):</p> </div>	<div data-bbox="1391 947 1412 993"> <p>Patient</p> </div>

METHYL SALICYLATE

methyl salicylate patch

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-8064(NDC:50488-2010)
Route of Administration	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: 6OZP39ZG8H)			
GLYCERIN (UNII: PDC6A3C00X)			
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (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				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-8064-1	2 in 1 BOX	08/16/2021	
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		08/16/2021	

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment			
Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-8064)

Revised: 8/2023 Preferred Pharmaceuticals Inc.