METHYL SALICYLATE- methyl salicylate 10% patch
Florrax Pharmaceutical Corp.

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 affected area
- Open pouch and remove one patch
- Remove any protective film and apply directly to affected area of pain. Apply immediately after removal form 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 of pieces of cut patches where children and pets cannot get to them.

Children under 18 years: Ask a physician

Purpose

External 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 healthcare professional. Read all warnings and directions before us. 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

Allergy Alert: if you are allergic to capsicum or chili peppers or any inactive ingredient of this product, contact a doctor before use.

When using this product

- You may experience a burning sensation. The intensity of this reaction varies among individuals and may be severe. With regular use, this sensatoin generally disappears after several days.
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- Avoid contact with the eyes, lips, nose and mucous membranes
- Do not tightly wrap or bandage the treated area
- Do no apply heat to the treated area immediately before or after use

Stop use and ask a physician 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

KEEP OUT OF REACH OF CHILDREN

CONSULT PHYSICIAN FOR CHILDREN UNDER 18.

Active Ingredient

Methyl Salicylate 10%

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 Temparature

Inactive Ingredients

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

Drug Facts (Continued)

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Methyl Salicylate 10%

Purpose
External Analgesic

METHYL SALICYLATE

methyl salicylate 10% patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84460-103
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
EDETATE DISODIUM (UNII: 7FLD91C86K)	
KAOLIN (UNII: 24H4NWX5CO)	

METHYLPARABEN (UNII: A2I8C7HI9T)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84460-103-01	2 in 1 BOX	02/10/2025	
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)	02/10/2025	

Labeler - Florrax Pharmaceutical Corp. (119257612)

Revised: 2/2025

Florrax Pharmaceutical Corp.