

METHYL SALICYLATE 10%- methyl salicylate patch
ViolaCare, Inc.

Methyl Salicylate 10% Patch

Drug Facts

Active ingredients:

Methyl Salicylate 10% (NSAID: nonsteroidal anti-inflammatory drug)

Purpose

External analgesic

Uses

Temporarily relieves aches & pains of muscles & joints associated with:

- Stains
- Sprains
- Simple Backache
- Arthritis
- Bruises

Warnings

For external use only

Stomach bleeding warning: This product contains an NSAID, which may cause stomach bleeding.

The chance is small but higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing as NSAID (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product

Do not use

- on the face or rashes
- on wounds or damaged skin
- if allergic to aspirin or other NSAIDs
- with a heating pad
- when sweating (such as from exercise or heat)
- any patch from a pouch that has been open for 14 or more days

- right before or after heat surgery

Ask a doctor before use if

- you are allergic to topical products
- the stomach bleeding warning applies to you
- you are taking a diuretic
- you have high blood pressure, heart disease or kidney disease

When using this product

- wash hands after applying or removing patch. Avoid contact with eyes. If eye contact occurs, rinse thoroughly with the water.
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed.

Stop and ask a doctor if

- stomach pain or upset gets worse or lasts
- you feel faint, vomit blood or have bloody or black stools, These are signs of stomach bleeding.
- rash, itching or skin irritation develops condition worsens symptoms last for more than 3 days
- symptoms clear up and occur again within a few days.

If pregnant or breast-feeding, ask a doctor before use while breast-feeding and during the first 6 months of pregnancy. Do not use during the last 3 months of pregnancy because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. If put in mouth, get medical help or contact a Poison Control right away. Package not child resistant. Dispose of the used patches after folding sticky ends together.

Directions

Adults and Children 10 years of age and older:

- only use one patch at a time
- clean and dry affected area
- remove patch from backing film and apply to skin (see illustration)
- apply 1 patch to the affective area of intact skin up to 24 hours.
- do not use more than 2 patches per day do not use for more than 3 days in a row
- the used patch should be removed from the skin when a new one is applied

Other information

- Store at 20-25°C (66-77°F)
- Avoid storing product in direct sunlight
- Protect product from excessive moisture
- Some individuals may not experience pain relief until several hours after applying the patch

24 Hour Application

15 Patches

3.94 in x 5.5 in EACH

Packaged For:

ViolaCare Inc.

Parsippany, New Jersey, 07054

METHYL SALICYLATE 10%

methyl salicylate patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85231-101
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
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
POLYVINYL ALCOHOL (100000 MW) (UNII: 949E52Z6MY)	
WATER (UNII: 059QF0KO0R)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85231-101-15	15 in 1 BOX	05/01/2025	
1		1 in 1 POUCH		
1		10 q 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)	05/01/2025	

Labeler - ViolaCare, Inc. (119452160)

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ViolaCare, Inc.