VIVA PATCH- camphor, lidocaine, and methyl salicylate patch Advanced Rx Pharmacy of Tennessee, LLC

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.

VIVA Patch

DRUG FACTS
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Active Ingredient

Camphor 2%

Purpose

Topical Analgesic

Active Ingredient

Lidocaine 2.5%

Purpose

Topical Anesthetic

Active Ingredient

Methyl Salicylate 4%

(NSAID: nonsteroidal anti-inflammatory drug)

Purpose

Topical Analgesic

Uses

Temporarily relieves mild to moderate aches and pains of muscles and joints associated with:

- muscle soreness
- strains

- sprains
- arthritis
- simple backache
- muscle stiffness
- 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 other drugs containing an NSAID (Aspirin, Ibuprofen, Naproxen, or others)
- take a blood thinning (anticoagulant) or steroid drug
- have three or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Do not use

- on the face or rashes; on wounds or damaged skin
- in the eyes, mouth, or other mucous membranes
- on genitals
- with a heating pad
- if allergic to any NSAIDS
- right before or after heart surgery
- any patch from a pouch that has been opened for 7 or more days

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
- you are pregnant

When using this product

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

Stop use and consult your physician if

- stomach pain or upset gets worse or lasts
- rash, irritation, or itching develops
- you feel faint, vomit blood, or have bloody or black stools (these are signs of stomach bleeding)
- condition worsens

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 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 Center right away. Package not child resistant. Dispose of the used patches by folding sticky ends together.

Directions

Adults, or children over the age of 12:

• Apply patch to affected area 1 to 2 times daily or as directed.

Instructions for Use

- clean and dry affected area
- open pouch and remove one patch
- remove protective film from patch
- apply one patch to the affected area of pain and leave in place for 8 to 12 hours
- if pain lasts after using the first patch, a second patch may be applied for up to another 8 to 12 hours
- only use one patch at a time
- do not use more than 2 patches per day
- wash hands with soap and water after applying or removing patch
- reseal pouch containing unused patches immediately after each use

Children under 12 years of age: Do not use

Other Information

- some individuals may not experience pain relief until several minutes or hours after applying the patch
- store in a cool, dry place
- protect product from excessive moisture or sunlight
- store at 67-77°F (19-25°C)

Acrylic Acid, Aluminum Hydroxide, Carmellose Sodium, 2-Ethylhexyl Acrylate, Glycerin, Isopropyl Myristate, Methyl Acrylate, Nonoxynol-30, Polyacrylic Acid, Polysorbate 80, Sodium Polyacrylate, Sorbitan Sesquioleate, Starch, Talc, Tartaric Acid, Titanium Dioxide, Water

Terrain Pharmaceuticals

Reno, NV 89501

TerrainRx.com

877-985-8377

Get Back to Life TM

VIVAPatch.com

Engineered in Reno-Tahoe

Assembled in China

Lot Number:

Exp Date:

Principal Display Panel



NDC: 80425-0257-01 Source NDC: 53225-1030-01 Lot: XXXXXXXX Expires: 8/31/2025



VIVA 2,5-4-2 % PATCH #15 NDC: 80425-0257-01 Seurce NDC: 53225-1030-01 Lot: XXXXXXXXX Exp:8/31/2025

TERRAIN PHARMAC S/N: 000000149588

VIVA PATCH

SOOTHING PAIN RELIEF

LIDOCAINE - METHYL SALICYATE - CAMPHOR

- Reduced Scent
- Flexible & Form Fitting
- Deep Penetrating

• Fast Acting

15 Patches

VIVA PATCH

camphor, lidocaine, and methyl salicylate patch

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80425-0257(NDC:53225-1030)	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	2.5 mg in 100 mg	
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	2 mg in 100 mg	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII: O414PZ 4LPZ)	METHYL SALICYLATE	4 mg in 100 mg	

Inactive Ingredients				
Ingredient Name	Strength			
NONOXYNOL-30 (UNII: JJX07DG188)				
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)				
ACRYLIC ACID (UNII: J94PBK7X8S)				
POLYSORBATE 80 (UNII: 60ZP39ZG8H)				
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)				
STARCH, CORN (UNII: O8232NY3SJ)				
TALC (UNII: 7SEV7J4R1U)				
TARTARIC ACID (UNII: W4888I119H)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
WATER (UNII: 059QF0KO0R)				
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)				
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)				
2-ETHYLHEXYL ACRYLATE (UNII: HR49R9S6XG)				
GLYCERIN (UNII: PDC6A3C0OX)				
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)				
METHYL ACRYLATE (UNII: WC487PR91H)				
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:80425- 0257-1	5 in 1 BOX	05/12/2023		

Marketing Category	Application Number or Monograph Citation	Marketing Start	Marketing End	
Marketing Information				
1	8650 mg in 1 PATCH; Type 0: Not a Combination Product			
1	3 in 1 POUCH			

05/12/2023

Labeler - Advanced Rx Pharmacy of Tennessee, LLC (117023142)

part348

OTC monograph not

Establishment				
Name	Address	ID/FEI	Business Operations	
Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0257)	

Revised: 5/2023 Advanced Rx Pharmacy of Tennessee, LLC