

NUVIRA- capsaicin 0.025%, menthol 10%, methyl nicotinate 0.25%, methyl salicylate 10% patch
Strand Health Group

Nuvira Patch

Drug Facts

Active Ingredients

Capsaicin 0.025%

Menthol 10%

Methyl Nicotinate 0.25%

Methyl Salicylate 10% (NSAID)

Purpose

Counterirritant

Counterirritant

Counterirritant

Counterirritant

Uses

For the temporary relief of joint pain, muscle pain, and inflammation associated with:

- Arthritis
- Backache
- Discomfort
- Cramps
- Neckache
- Soreness
- Sprains
- Strains

This product may take up to 7 days to work for arthritis pain.

Warnings

For External Use Only Topical use only

Allergy Alert: NSAIDs may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- Hives

- Asthma (wheezing)
- Skin Reddening
- Blisters
- Facial Swelling
- Shock
- Rash

If an allergic reaction occurs, stop use and seek medical attention immediately.

Liver Warning: This product contains an NSAID. Liver damage may occur if you apply (1) more or for a longer time than directed or (2) when using other drugs containing an NSAID.

Stomach Bleeding Warning: This product contains an NSAID, which may cause severe 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 prescription or non-prescription NSAIDs (aspirin, ibuprofen, naproxen or others)
- Have 3 or more alcoholic drinks every day while using this product
- Apply more or for longer than directed

Heart Attack and Stroke Warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do Not Use

- On damaged, irritated, or infected skin
- With a bandage or heating pad
- If you are allergic to any ingredients in this product
- Right before or after heart surgery
- In the eyes, nose, or mouth
- Otherwise as directed

When Using This Product

Avoid contact with the eyes and mucous membranes

Stop Use and Ask a Doctor If

- Any of the Warnings apply to you
- You are taking a diuretic
- You are taking any other drugs
- You have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- Excessive skin irritation develops
- Condition worsens
- Symptoms persist for more than 7 days, or symptoms clear up and occur again

within 3 days

If Pregnant or Breast-Feeding

Ask a health professional before use. It is especially important not to use NSAIDs at 20 weeks or later in pregnancy, unless directed by a doctor to do so.

Keep Out of Reach of Children

If ingested seek medical help or contact a Poison Control Center immediately

Flammable

Keep away from excessive heat or open flame

Directions

Adults and Children 12 Years of Age and Older:

- Clean and dry the affected area
- Apply gel pad directly to your skin for up to 12 hours
- Gel pad can be cut into pieces and used on up to 2 body parts at a time
- One application per day is recommended
- Wash hands immediately after use

Other Information

- Store in a cool, dry place with lid tightly closed.
- If the tamper-evident foil seal is not intact, do not use

Inactive Ingredients

Aloe Vera Gel, Arnica, Boswellia, Citris Limon (Lemon Oil), Dihydroxyaluminum Aminoacetate, Dimethyl Sulfone (DMSO2), Eucalyptus Oil, Glycerol, Methylparaben, Polyacrylic Acid, Prunis Amygdalus Dulcis (Almond Oil), Pure Water, Sodium Polyacrylate, Sorbitol, Vitamin C, Vitamin E.

Questions or Comments?

cs@strandhealthgroup.com

Principal Display Panel



NUVIRA®
PAIN RELIEF PATCH

CAPSAICIN
MENTHOL

METHYL NICOTINATE
METHYL SALICYLATE

WITH VITAMIN C, VITAMIN E, DMSO2,
ALMOND OIL, EUCALYPTUS OIL, LEMON OIL,
BOSWELLIA, ALOE VERA, AND ARNICA.

5 PATCHES
CUTANEOUS
NDC 83295-3313-5



DRUG FACTS	
Active Ingredients	Purpose
Capsaicin 0.025%	Counterirritant
Menthol 10%	Counterirritant
Methyl Nicotinate 0.25%	Counterirritant
Methyl Salicylate 10% (NSAID)	Counterirritant
Uses	
For the temporary relief of joint pain, muscle pain, and inflammation associated with: • Arthritis • Backache • Discomfort • Cramps • Neckache • Soreness • Sprains • Strains. This product may take up to 7 days to work for arthritis pain.	
Warnings	
For External Use Only	
Allergy Alert: NSAIDs may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: • Hives • Asthma (wheezing) • Skin Reddening • Blisters • Facial Swelling • Shock • Rash. If an allergic reaction occurs, stop use and seek medical attention immediately.	
Liver Warning: This product contains an NSAID. Liver damage may occur if you apply (1) more or for a longer time than directed or (2) when using other drugs containing an NSAID.	
Heart Attack and Stroke Warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.	
Stomach Bleeding Warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is small, but higher if you: <ul style="list-style-type: none"> • Are age 60 or older • Have had stomach ulcers or bleeding problems • Take a blood thinner (anticoagulant) or steroid drug • Have 3 or more alcoholic drinks every day while using this product <ul style="list-style-type: none"> • Take other drugs containing prescription or non-prescription NSAIDs (aspirin, ibuprofen, naproxen or others) • Apply more or for longer than directed 	
Do Not Use: <ul style="list-style-type: none"> • On damaged, irritated, or infected skin • With a bandage or heating pad • If you are allergic to any ingredients in this product • Right before or after heart surgery • In the eyes, nose, or mouth • Otherwise as directed 	
When Using This Product: Avoid contact with the eyes and mucous membranes	
Stop Use and Ask a Doctor if: <ul style="list-style-type: none"> • Any of the Warnings apply to you • You are taking a diuretic • You are taking any other drugs • You have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke • Excessive skin irritation develops • Condition worsens • Symptoms persist for more than 7 days, or symptoms clear up and occur again within 3 days 	
If Pregnant or Breast-Feeding: Ask a health professional before use. It is especially important not to use NSAIDs at 20 weeks or later in pregnancy, unless directed by a doctor to do so.	
Keep Out of Reach of Children: If ingested seek medical help or contact a Poison Control Center immediately	
Flammable: Keep away from excessive heat or open flame	
Directions	
Adults and Children 12 Years of Age and Older: <ul style="list-style-type: none"> • Clean and dry the affected area • Apply gel pad directly to your skin for up to 12 hours • Gel pad can be cut into pieces and used on up to 2 body parts at a time • One application per day is recommended • Wash hands immediately after use 	
Other Information <ul style="list-style-type: none"> • Store in a cool, dry place avoiding direct sunlight • Avoid extreme moisture while storing 	
Inactive Ingredients: Aloe Vera Gel, Arnica, Boswellia, Citrus Limon (Lemon Oil), Dihydroxyaluminum Aminoacetate, Dimethyl Sulfoxide (DMSO), Eucalyptus Oil, Glycerol, Methylparaben, Polyacrylic Acid, Prunus Amygdalus Dulcis (Almond Oil), Pure Water, Sodium Polyacrylate, Sorbitol, Vitamin C, Vitamin E.	
Questions or Comments? strandhealthgroup.com	

NUVIRA

capsaicin 0.025%, menthol 10%, methyl nicotinate 0.25%, methyl salicylate 10% patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83295-3313
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL NICOTINATE (UNII: 7B1AVU9DJN) (NIACIN - UNII:2679MF687A)	METHYL NICOTINATE	0.0025 g in 1 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.1 g in 1 g
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.00025 g in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.1 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM POLYACRYLATE (250000 MW) (UNII: 05115JN12J)	
WATER (UNII: 059QF0KO0R)	

SORBITOL (UNII: 506T60A25R)
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)
METHYLPARABEN (UNII: A2I8C7HI9T)
EUCALYPTUS OIL (UNII: 2R04ONI662)
GLYCERIN (UNII: PDC6A3C0OX)
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)
ASCORBIC ACID (UNII: PQ6CK8PD0R)
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
FRANKINCENSE (UNII: R9XLF1R1WM)
LEMON OIL, DISTILLED (UNII: ET5GD00TRP)
ALMOND OIL (UNII: 66YXD4DKO9)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83295-3313-5	5 in 1 POUCH	06/29/2023	
1		8.5 g in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:83295-3313-1	6 in 1 BOX	06/29/2023	
2		5 in 1 POUCH		
2		8.5 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	M017	06/29/2023	

Labeler - Strand Health Group (118929144)