

## **PAINSHIELD- menthol cream**

**Nutranext 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.*

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### **PainShield cream**

#### ***Drug facts***

##### ***Active ingredient***

Menthol USP 3.7%

##### ***Purpose***

Topical analgesic

**Uses** temporarily relieves minor aches and pains of muscles and joints due to

- arthritis
- simple backaches
- strains
- bruises
- sprains

##### ***Warnings***

**For external use only Flammable:** Keep away from fire or flame.

##### **Do not use**

- on wounds or damaged skin
- with a heating pad
- with other ointments, creams, sprays or liniments

##### **When using this product**

- avoid contact with eyes
- do not bandage tightly
- wash hands with cool water after use

##### **Stop use and ask a doctor if**

- condition worsens or rash or irritation develops
- symptoms last more than 7 days
- condition clears up and occurs again within a few days

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

##### ***Directions***

**adults and children 12 years of age and older:** apply and massage onto affected area no more than 3 to 4 times daily

**children under 12 years of age:** ask a doctor

##### ***Other information***

- close cap tightly
- store in a cool, dry place

**Inactive ingredients** Aloe Barbadensis Leaf Extract, Arnica Montana Flower Extract, Carbomer, Dimethyl Sulfone(MSM), EDTA, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Melaleuca Altemifolia (Tea Tree) Leaf Oil, Pyridoxine HCl (Vitamins B6), Phenoxyethanol & Methyl/Ethyl/Butyl/Propyl/Isobutylparabens, Polysorbate 20, Purified Water, Tocopheryl (Vitamin E) Acetate, Triethanolamine

**Manufactured and Distributed by Stop Aging Now as Nutranext Direct, LLC**

1301 Sawgrass Corporate Parkway, Sunrise, FL 33323 • 800-627-9721

NDC# 72914-0001-1

PainShield™

Advanced Pain Relief Cream for Arthritis, Joint, Muscle and Back Pain

Cooling Menthol

Net Wt. 6 oz. (170 grams)

**Drug Facts (continued)**  
**Stop use and ask a doctor if** • condition worsens or rash or irritation develops  
 • symptoms last more than 7 days • condition clears up and occurs again within a few days  
**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.  
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## PAINSHIELD

menthol cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72914-0001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3.7 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B404F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
2-(2-(2-(2-PHENOXYETHOXY)ETHOXY)ETHOXY)ETHANOL (UNII: Y050HYR4XA)	
WATER (UNII: 059QF0K00R)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	

<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>ISOBUTYLPARABEN</b> (UNII: 0QJ25X58G)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>MELALEUCA ALTERNIFOLIA LEAF</b> (UNII: G43C57162K)	
<b>DIMETHYL SULFONE</b> (UNII: 9H4PO4Z4FT)	
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV)	
<b>METHYLPARABEN</b> (UNII: A218C7HI9T)	
<b>ETHYLPARABEN</b> (UNII: 14255EXE39)	
<b>BUTYLPARABEN</b> (UNII: 3QPIIU3FV8)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72914-0001-1	170 g in 1 JAR; Type 0: Not a Combination Product	03/15/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/15/2019	

**Labeler** - Nutranext LLC (968031174)

### Establishment

Name	Address	ID/FEI	Business Operations
Accupack Midwest		139637433	manufacture(72914-0001)

Revised: 3/2019

Nutranext LLC