

PAINFIX RESTORE- menthol patch

PainFix 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.

PainFix Restore Patch

Drug Facts

Active Ingredients

Menthol 3%

Purpose

Topical analgesic

Uses

Temporarily relieves aches and pains of joints and muscles associated with: • backache • arthritis • bursitis • tendonitis • cramps • strains • bruises • sprains

Warnings

Avoid direct contact with eyes. For external use only.

When using this product

• use only as directed • avoid contact with eyes or mucous membranes • do not apply local heat to the area of use • do not apply to wounds, broken, damaged or irritated skin

Stop use and ask a doctor if

• condition worsens or symptoms persist for more than 7 days • skin irritation develops or you experience signs of skin injury, such as pain, swelling, or blistering where product is applied

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

If pregnant or breast-feeding,

ask a health professional before use.

Directions

Adults and children above 12 years:

- open pouch and remove patch
- peel off protective backing and carefully apply sticky side to affected area
- if affected area is large, use more than one patch for best results
- use each patch for up to 15 hours
- apply a new patch each day
- to better keep the patch in place, use the provided adhesive plasters
- for best results, use with recommended exercises

Children 12 years and younger, ask a health professional

Other Information

Store in a cool, dry place, away from direct sunlight.

Ingredients

Aloe barbadensis extract, Aluminum glycinate, Angelica anomala extract, Carthamus tinctorius extract, Cinnamomum camphora extract, Cinnamomum cassia extract, Citrus reticulata extract, Commiphora molmol extract, Curcuma longa extract, Curcuma zedoaria extract, Daemonops draco extract, Disodium EDTA, Drynaria fortunei extract, Glycerine, Glyceryl stearate, Kaolin, Methylparaben, PEG-40 hydrogenated castor oil, Pistacia lentiscus extract, Polyvinylpyrrolidone, Rheum officinale extract, Sodium polyacrylate, Scutellaria baicalenis extract, Tartaric acid, Water (Aqua)

Package Labeling:



Restore Patch

PainFix



Welcome to our community. Share your #UnlockedBody story:

www.painfixbody.com

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PAINFIX RESTORE

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72749-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
KAOLIN (UNII: 24H4NWX5CO)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
TARTARIC ACID (UNII: W4888I119H)	
WATER (UNII: 059QF0K00R)	
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
TURMERIC (UNII: 856YO1Z64F)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72749-000-00	5 in 1 BOX	02/01/2019	
1		1 in 1 PACKET		
1		573 mL 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 not final	part348	02/01/2019	

Labeler - PainFix LLC (116908667)

Revised: 2/2019

PainFix LLC