## GOODSENSE EXTRA STRENGTH COLD AND HOT MEDICATED- menthol patch Geiss, Destin and Dunn, Inc.

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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## Goodsense Cold & Hot Patch (125)

# Active ingredient Purpose Menthol 5%......Topical analgesic

#### Uses

temporariliy relieves minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- burises
- sprains

## Warnings

## For external use only

Do not use

- on wonunds or damaged skin
- with a heating pad
- on a child under 12 years of age with arthritis-like conditions

Ask a doctor before use if you have

redness over the affected area

## When using this product:

- use only as directed
- avoid contact with eyes or mucous membranes
- do not bandage tightly
- discontinue use at least 1 hour before a bath or shower
- do not use immediately after a bath or shower

## Stop use and ask a doctor if:

- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- excessive skin irritation occurs

If pregnant or breast-feeding, ask a health professional before use.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

#### **Directions**

• open pouch and remove patch

- carefully peel off protective backing and apply sticky side to affected area
- adults and children 12 years of age or older
- do not wear patch for more than 8 hours
- apply to affected area no more than 3 times daily
- children under 12 years of age: consult a doctor

#### Other information

• Store at room temperature 20-25°C (68-77°F)

## **Inactive ingredients**

alcohol, aluminum glycinate, glycerin, kaolin, methylparaben, polysorbate 80, propylparaben, purified water, sodium polyacrylate, sorbitan monooleate, tartaric acid, titanium dioxide

Distributed By:

Perrigo Direct, Inc.

Peachtree City, Ga 30269

www.PerrigoDirect.com

1-866-696-0957

Made in China



## **GOODSENSE EXTRA STRENGTH COLD AND HOT MEDICATED**

menthol patch

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50804-126	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	50 mg	

Inactive Ingredients	
Ingredient Name	Strength
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
KAOLIN (UNII: 24H4NWX5CO)	
ALCOHOL (UNII: 3K9958V90M)	

GLYCERIN (UNII: PDC6A3C0OX)
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)
PROPYLPARABEN (UNII: Z8IX2SC10H)
METHYLPARABEN (UNII: A2I8C7HI9T)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)
TARTARIC ACID (UNII: W48881119H)
WATER (UNII: 059QF0KO0R)

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50804-126- 05	1 in 1 CARTON	12/26/2018	
1		5 in 1 POUCH; 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	12/26/2018	

Labeler - Geiss, Destin and Dunn, Inc. (076059836)

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