# MEDIRELIEF ULTRA- menthol patch FARLA MEDICAL INT LTD

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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#### MediRelief Ultra Strength Menthol 5% Patch

#### **Drug Facts**

#### **Active Ingredients & Purpose**

## Active ingredients (in each patch) Purpose

Menthol 5%......Topical analgesic

#### Uses

For the temporary relief of minor aches and pains of muscles and joints associated with  $\square$  simple backache  $\square$  arthritis  $\square$  strains  $\square$  sprains

#### Warnings

**FOR EXTERNAL USE ONLY**. Avoid contact with the eyes.

#### Do not use

□ on wounds or damaged skin □ on a tight bandage □ with a heating pad

□ on sensitive skin □ if allergic to any ingredients in this product

#### Stop use and ask a doctor if

☐ condition worsens ☐ redness is present

□ symptoms persist for more than 7 days or clear up and occur again within a few days

#### If pregnant of 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 right away.

#### Directions

☐ adults & children 12 years of age and older: apply to affected area not more than 3 to 4 times daily ☐ children under 12 years of age: consult a doctor

#### Other Information

□ store at room temperature 68-77°F (20-25°C) □ do not store in direct sunlight or expose to excessive heat and moisture

**TAMPER EVIDENT:** Do not use if pouch containing the patch is torn or broken.

## **Inactive Ingredients**

dihydroxyaluminum aminoacetate, glycerin, kaolin,

methylparaben, polyacrylic acid, polysorbate 80, povidones, propylene glycol, propylparaben, sodium polyacrylate, tartaric acid, titanium dioxide, water

#### **Principal Display Panel**



(Medium) Patch NDC 73486-101-25

(Large) Patch NDC 73486-101-35

## **MEDIRELIEF ULTRA**

menthol patch

Product Information	Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73486-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10 EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10 EIP3A)	MENTHOL, UNSPECIFIED FORM	5 g	

Inactive Ingredients		
	Ingredient Name	Strength

PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
DIHYDROXYALUMINUM AMINO ACETATE ANHYDROUS (UNII: 1K713C615K)	
PO VIDO NE (UNII: FZ989 GH94E)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
KAOLIN (UNII: 24H4NWX5CO)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
TARTARIC ACID (UNII: W4888I119H)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73486-101-25	5 in 1 CARTON	05/04/2020	
1		1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:73486-101-35	5 in 1 CARTON	05/04/2020	
2		1 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	05/04/2020	

## Labeler - FARLA MEDICAL INT LTD (221985675)

Revised: 5/2020 FARLA MEDICAL INT LTD