PARCHE LEON MILAGROSO DUAL ACTION- capsaicin, menthol patch Pharmadel 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.

Parche Leon Milagroso Dual Action

Drug Facts

Active Ingredients

Capsaicin 0.0375%

Menthol 5%

Purpose

Topical Analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with

- simple backaches
- arthritis
- strains
- sprains

Warnings

FOR EXTERNAL USE ONLY. Avoid contact with the eyes.

Allergy Alert: This product contains natural rubber latex which may cause allergy reactions.

Do not use

- on wounds or damaged skin
- with a bandage or heating pad
- on sensitive skin
- if allergic to any ingredients in this product

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days
- redness is present

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 right away.

Directions

- adults & children 12 yrs of age & older: apply to affected area not more than 3 to 4 times daily
- children under 2 year of age: consult a doctor
- clean and dry affected area
- remove patch from film
- apply sticky side of patch to affected area
- use one patch at a time
- leave patch on affected area for up to 8-hours at a time

Inactive ingredients:

aloe barbadensis leaf (aloe vera gel) juice, diazolidinyl urea, EDTA disodium, glycerin, iodopropynyl butylcarbamate, methylparaben, polysorbate 80, propylparaben, sodium polyacrylate, water.

Other information:

- store at room temperature 59-86°F (15-30°C)
- do not store in direct sunlight or expose to excessive heat

TAMPER EVIDENT:

Do not use if packet containing the patch is torn or broken.

Questions & comments?

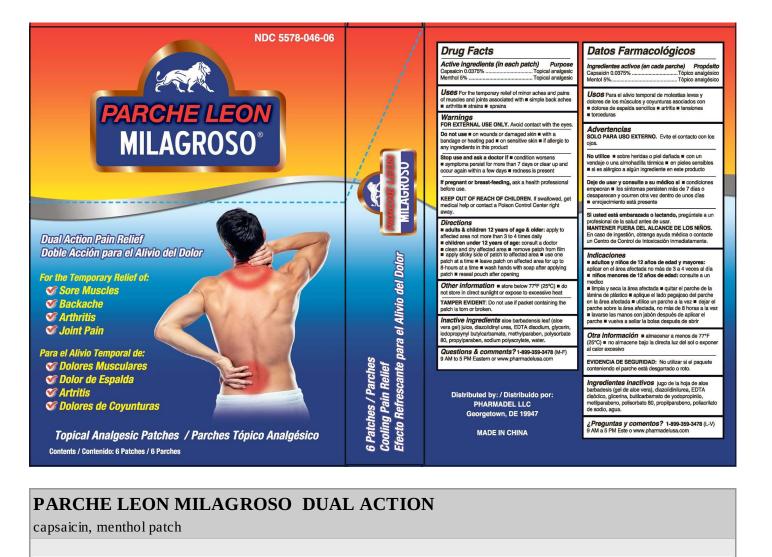
1-899-359-3478 (M-F) 9 AM to 5 PM Eastern or www.pharmadelusa.com

Topical Analgesic Patches

Dual Action Pain Relief

For the temporary relief of:

- Sore Muscules
- Backache
- Arthritis
- Joint Pain



Product Information						
Product T ype	HUMAN OTC DRUG	Item Code (Source)		NDC:55758-046		
Route of Administration	TOPICAL					
Active Ingradient/Active Mei	A 4 4 7					
Active Ingredient/Active Moiety						
Ingredient Name			Basis of Strength	ı Strength		
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)			MENTHOL	5 g in 100 g		
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)			CAPSAICIN	0.0375 g in 100 g		
Inactive Ingredients						

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05115JNI2J)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

PROPYLPARABEN (U	NII: 281225C10H)					
WATER (UNII: 059QF0	KO0R)					
Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
1 NDC:55758-046-06	6 in 1 CARTON	0 2/0 1/20 16				
1	2.27 g in 1 POUCH; Type 0: Not a Combination Product					
Marketing Information						
Marketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not fin	al part348	0 2/0 1/20 16				

Labeler - Pharmadel LLC (026095439)

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Pharmadel LLC