

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 Muscles
- Backache
- Arthritis
- Joint Pain

NDC 5578-046-06



Dual Action Pain Relief
Doble Acción para el Alivio del Dolor

For the Temporary Relief of:

- ✔ Sore Muscles
- ✔ Backache
- ✔ Arthritis
- ✔ Joint Pain

Para el Alivio Temporal de:

- ✔ Dolores Musculares
- ✔ Dolor de Espalda
- ✔ Artritis
- ✔ Dolores de Coyunturas



Topical Analgesic Patches / Parches Tópico Analgésico

Contents / Contenido: 6 Patches / 6 Parches

6 Patches / Parches
Cooling Pain Relief
Efecto Refrescante para el Alivio del Dolor

Drug Facts

Active Ingredients (In each patch) Purpose
 Capsaicin 0.0375% Topical analgesic
 Menthol 5% Topical analgesic

Uses For the temporary relief of minor aches and pains of muscles and joints associated with simple back aches
 ■ arthritis ■ strains ■ sprains

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

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 years of age & older: apply to affected area not more than 3 to 4 times daily
 ■ children under 12 years 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 ■ wash hands with soap after applying patch ■ reseal pouch after opening

Other information ■ store below 77°F (25°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.

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

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

Distributed by: / Distribuido por:
 PHARMADEL LLC
 Georgetown, DE 19947

MADE IN CHINA

Datos Farmacológicos

Ingredientes activos (en cada parche) Propósito
 Capsaicin 0.0375% Tópico analgésico
 Menthol 5% Tópico analgésico

Usos Para el alivio temporal de molestias leves y dolores de los músculos y coyunturas asociados con
 ■ dolores de espalda sencillos ■ artritis ■ tensiones ■ torceduras

Advertencias
SOLO PARA USO EXTERNO. Evite el contacto con los ojos.

No utilice ■ sobre heridas o piel dañada ■ con un vendaje o una almohadilla térmica ■ en pieles sensibles ■ si es alérgico a algún ingrediente en este producto

Deje de usar y consulte a su médico si ■ condiciones empeoran ■ los síntomas persisten más de 7 días o desaparecen y ocurren otra vez dentro de unos días ■ enrojecimiento está presente

Si usted está embarazada o lactando, pregúntele a un profesional de la salud antes de usar.
MANTENER FUERA DEL ALCANCE DE LOS NIÑOS. En caso de ingestión, obtenga ayuda médica o contacte un Centro de Control de Intoxicación inmediatamente.

Indicaciones

■ adultos y niños de 12 años de edad y mayores: aplicar en la área afectada no más de 3 a 4 veces al día
 ■ niños menores de 12 años de edad: consulte a un médico

■ limpie y seque la área afectada ■ quitar el parche de la lámina de plástico ■ aplique el lado pegajoso del parche en la área afectada ■ utilice un parche a la vez ■ dejar el parche sobre la área afectada, no más de 8 horas a la vez ■ lavarse las manos con jabón después de aplicar el parche ■ vuelva a sellar la bolsa después de abrir

Otra información ■ almacenar a menos de 77°F (25°C) ■ no almacene bajo la directa luz del sol o exponer al calor excesivo

EVIDENCIA DE SEGURIDAD: No utilizar si el paquete conteniendo el parche está desgarrado o roto.

Ingredientes inactivos jugo de la hoja de aloe barbadensis (gel de aloe vera), diazolidinilurea, EDTA disódico, glicerina, butilcarbamato de yodopropililo, metilparabeno, polisorbato 80, propilparabeno, poliacrilato de sodio, agua.

¿Preguntas y comentarios? 1-899-359-3478 (L-V) 9 AM a 5 PM Este o www.pharmadelusa.com

PARCHE LEON MILAGROSO DUAL ACTION

capsaicin, menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55758-046
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	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 (250000 MW) (UNII: 05115JN2J)	
METHYL PARABEN (UNII: A218C7HI9T)	
IODOPROPYNYL BUTYL CARBAMATE (UNII: 603P14DHEB)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-046-06	6 in 1 CARTON	02/01/2016	
1		2.27 g 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	02/01/2016	

Labeler - Pharmadel LLC (026095439)

Revised: 7/2016

Pharmadel LLC