

CMC PAIN RELIEVING- .alpha.,.alpha.-dibromo-d-camphor, menthol, unspecified form, and capsaicin patch

Unexo Life Sciences, Private Limited

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.

CMC Pain Relieving Patch

Drug Facts

Active Ingredient

Camphor 3%	External Analgesic
Menthol 1.25%	External Analgesic
Capsaicin 0.025%	External Analgesic

Uses

For 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 eyes.

Do not use

- On wounds or damaged skin
- With a bandage or heating pad
- On sensitive skin
- if allergic to any ingredient in this product

Stop use and ask a doctor if

- Condition worsens
- symptoms persist for more than 7 days
- 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 and children 12 years of age and older: apply to the 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

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

Inactive Ingredients

Adhesive plaster

Questions

Call +91 9212228401

Manufactured By:

UNEXO LIFE SCIENCES PVT. LTD.
B-16, Sector 4, Bawana Industrial Area,
Delhi – 110039 (INDIA)

PRINCIPAL DISPLAY PANEL - 6 Pouch Box

NDC: 71391-125-06

UNEXO's
PAIN RELIEVING
HOT PATCH

External Analgesic

Penetrating pain relief for:

- Back Aches
- Muscles
- Arthritis

6

Adhesive Plaster Patches

4.72 in x 7.07 in (12 cm x 18 cm)

NDC: 71391-125-06

UNEXO's PAIN RELIEVING HOT PATCH

External Analgesic • Analgésico Externo

Penetrating pain relief for:

- Back Aches
- Muscles
- Arthritis

Alivio penetrante para los dolores de:

- Espalda
- Muscular
- Artritis

6

Adhesive Plaster Patches
Parches Adhesivos
4.72 in x 7.07 in (12 cm x 18 cm)



Pain Relieving
HOT PATCH



Drug Facts

Active ingredients (in each patch)	Purpose
Camphor 3% Menthol 1.25% Capsaicin 0.025%	} External 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.

Datos Farmacológicos

Ingredientes activos (en cada parche)	Propósito
Alcanfor 3% Mentol 1.25% Capsaicina 0.025%	} Analgésico externo

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.

L
or

FOR EXTERNAL USE ONLY. AVOID CONTACT WITH THE EYES.

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

Inactive ingredients : Adhesive plaster

Questions & comments? +91 9212228401

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 Delhi - 110039 (INDIA)
 Phone: +91 9212228401
 Email: info@unexopharma.com

SÓLO 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 el área afectada no más de 3 a 4 veces al día
- niños menores de 12 años de edad: consulte a un médico
- limpia y seca el área afectada quitar el parche de la lámina de plástico aplique el lado pegajoso del parche en el área afectada utilice un parche a la vez deje el parche sobre el área afectada, no más de 8 horas a la vez

Otra información

- almacenar en temperatura ambiente entre 59-86°F (15-30°C) no almacene bajo la luz directa del sol o exponer al calor excesivo

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

Ingredientes inactivos: esparadrappo

¿Preguntas y comentarios? +91 9212228401

NDC: 71391-125-06
 NC/DL-378-A&U
 Made in India

PARCHE TERMA
 Para el Alivio de dolor

Pain Relieving
HOT PATCH

CMC PAIN RELIEVING

.alpha.,.alpha.-dibromo-d-camphor, menthol, unspecified form, and capsaicin patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71391-125
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
.ALPHA.,.ALPHA.-DIBROMO-D-CAMPHOR (UNII: F89Z8SAG3O) (.ALPHA.,.ALPHA.-DIBROMO-D-CAMPHOR - UNII:F89Z8SAG3O)	.ALPHA.,.ALPHA.-DIBROMO-D-CAMPHOR	129.6 mg
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	54 mg
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	1.08 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71391-125-01	1 in 1 POUCH; Type 0: Not a Combination Product	06/01/2020	
2	NDC:71391-125-06	6 in 1 BOX	06/01/2020	
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	06/01/2020	

Labeler - Unexo Life Sciences, Private Limited (872260479)

Establishment

Name	Address	ID/FEI	Business Operations
Unexo Life Sciences, Private Limited		872260479	MANUFACTURE(71391-125)

Revised: 5/2020

Unexo Life Sciences, Private Limited