

PASMOL PAIN RELIEVING- menthol and methyl salicylate cream

Grafor, 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.

Pasmol Pain Relieving Ointment

Active ingredients

Menthol 5%

Methyl Salicylate 14%

Purpose

Pain Relieving

Uses

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

- Arthritis
- simple backache
- bruises
- sprains

Warnings

For external use only.

Do not use

- in the eyes
- on mucous membranes
- on wounds or damaged skin

When using this product

- do not bandage tightly

Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days or clear up and occur again within a few day
- redness is present
- excessive irritation of the skin develops

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children three years of age and older: apply to affected area not more than 3-4 times daily.
- Children under 3 years of age: consult a doctor

Inactive ingredients

PETROLATUM

MANUFACTURED BY GRAFOR INC. 1360 CASTELLANAS ST LA RAMBLA PONCE, PR 00730
 UNITED STATES (787) 842-1423 WWW.PASMOL.COM REPORT ADVERSE EVENTS TO
 GRAFOR INC.

Pasmol Pain Relieving Ointment, 85g (61361-820-03)

PASMOL

“Arthritis Formula”

“Formula Arthritis”

Pain Relieving Ointment

Net Wt./ Peso Neto 3 oz (85 g)

MANUFACTURED BY GRAFOR INC. 1360 CASTELLANAS ST LA RAMBLA PONCE, PR 00730 UNITED STATES (787) 842-1423 WWW.PASMOL.COM REPORT ADVERSE EVENTS TO GRAFOR INC. ANCHORAGE, ALASKA	Drug Facts (continued) When using this product <input type="checkbox"/> do not bandage tightly Stop use and ask a doctor if <input type="checkbox"/> condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days <input type="checkbox"/> redness is present <input type="checkbox"/> excessive irritation of the skin develops Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	PASMOL [®] NDC 61361-820-03 “Arthritis Formula” “Formula Arthritis” Pain Relieving Ointment Ungüento para Aliviar el Dolor Net Wt./ Peso Neto 3 oz (85 g)	Datos del Medicamento (continuará) Al usar este producto <input type="checkbox"/> no ajustar el vendaje Detenga su uso y consulte a un médico si <input type="checkbox"/> la condición empeora o si los síntomas persisten por más de 7 días, se mejoran y recaen nuevamente unos cuantos días después. <input type="checkbox"/> se presenta enrojecimiento <input type="checkbox"/> y/o irritación excesiva de la piel. Manténgase fuera del alcance de los niños. En caso de ingestión, solicite ayuda médica o acuda a un hospital inmediatamente.	
	Directions <input type="checkbox"/> Adults and children three years of age and older: apply to affected area not more than 3-4 times daily. <input type="checkbox"/> Children under 3 years of age: consult a doctor. Inactive ingredients PETROLATUM		Instrucciones <input type="checkbox"/> Adultos y niños mayores de 3 años: aplique al área afectada no más de 4 veces al día. <input type="checkbox"/> Niños menores de 3 años: consultar a un médico Ingredientes Inactivos PETROLATO	

Drug Facts	
Active ingredients	Purpose
Menthol 5% Methyl Salicylate 14%	Pain Relieving
Use For the temporary relief of minor aches and pains of the muscles and joints associated with <input type="checkbox"/> Arthritis <input type="checkbox"/> simple backache <input type="checkbox"/> bruises <input type="checkbox"/> sprains	
Warnings For external use only Do not use <input type="checkbox"/> in the eyes <input type="checkbox"/> on mucous membranes <input type="checkbox"/> on wounds or damaged skin	
<i>peel away</i> ▶	

Ingredientes Activos	
Ingredientes Activos	Uso
Mentol 5% Salicilato de Metilo 14%	Aliviar el Dolor
Uso Para aliviar temporalmente los dolores de músculos y articulaciones menores asociados con <input type="checkbox"/> Arthritis <input type="checkbox"/> Dolor de Espalda Simple <input type="checkbox"/> Moretones <input type="checkbox"/> Esquinces	
Advertencias Solo para uso externo No utilizarse <input type="checkbox"/> en los ojos <input type="checkbox"/> en las membranas mucosas <input type="checkbox"/> en heridas o piel dañada	
<i>etiqueta desplegable</i> ▶	

PASMOL PAIN RELIEVING

menthol and methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61361-820
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
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	14 g in 100 g

Inactive Ingredients

Ingredient Name		Strength		
PETROLATUM (UNII: 4T6H12BN9U)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61361-820-03	85 g in 1 JAR; 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	04/08/2015		

Labeler - Grafor, Inc. (135138811)

Establishment			
Name	Address	ID/FEI	Business Operations
Grafor, Inc.		135138811	manufacture(61361-820)

Revised: 4/2015

Grafor, Inc.