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)

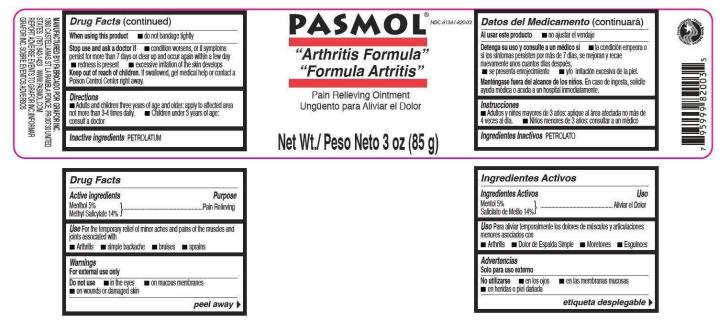
PASMOL

"Arthritis Formula"

"Formula Artritis"

Pain Relieving Ointment

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



PASMOL PAIN RELIE	VING								
menthol and methyl salicylate cr	ream								
Product Information									
Product T ype	HUMAN OTC DRUG	Item Code (Sour	Item Code (Source)		NDC:61361-820				
Route of Administration	TOPICAL								
Active Ingredient/Active Moiety									
1	Basis of Strength		Strength						
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)				MENTHOL					
METHYL SALICYLATE (UNII: LAV	METHYL SALICYLATE		14 g in 100 g						

Inactive Ingredients

Ingredient Name					Strength		
PETROLATUM (UNII: 4							
Packaging							
# Item Code		Package Description Marketing Start Da		rketing Start Date	Marketing End Date		
1 NDC:61361-820-03	85 g in 1	in 1 JAR; Type 0: Not a Combination Product					
Marketing Information							
Marketing Category Application Number or Monograph Cita		tion	Marketing Start Da	te Marketing End Date			
OTC MONOGRAPH NOT	TC 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.