TOPCARE HEALTH PAIN RELIEF- menthol, camphor, and methyl salicylate patch Topco Associates 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.

Active ingredients Purposes

Camphor 1.2%......Topical analgesic

Menthol 5.7%......Topical analgesic

Methyl salicylate 6.3%.....Topical analgesic

Uses

- temporarily relieves the minor aches and pains of muscles and joints associated with:
- sprains
- simple backache
- arthritis
- strains
- bruises

Warnings

For external use only

Allergy alert: If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

Do not use

- on wounds or damaged skin
- with a heating pad
- if you are allergic to any ingredients of this product
- on a child under 12 years of age with arthritis-like conditions

Ask a doctor before use if you have redness over the affected area.

When using this product

- do not use otherwise than as directed
- avoid contact with eyes, mucous membranes or rashes
- do not bandage tightly
- discontinue use at least 1 hour before a bath or shower
- do not use immediately after a bath or shower

Stop use and ask a doctor if

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

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 (1-800-222-1222) right away.

Directions

- adults and children 12 years of age and older:
- clean and dry affected area
- remove patch from film
- apply to affected area no more than 3 to 4 times daily
- do not wear patch for more than 4 hours
- children under 12 years of age: consult a doctor

Other information

- store at room temperature 20-25°C (68-77°F)
- avoid storing product in direct sunlight
- protect product from excessive moisture

Inactive ingredients

glyceryl rosinate, lanolin, natural latex rubber, petrolatum, polyisobutylene, zinc oxide

Distributed by:

Topco Associates LLC

Elk Grove IL 60007

Made in China



menthol, camphor, and methyl salicylate patch

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-670
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.012 mg in 1 g		
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.057 mg in 1 g		
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ4LPZ)	METHYL SALICYLATE	0.063 mg in 1 g		

Ingredient Name		Strongth
		Strength
E (UNII: SD112V492J)		
BBER (UNII: 2LQOUUW8IN)		
4T6H12BN9U)		
DI2LOH54Z)		
(1000 MW) (UNII: 5XB3A63Y52)		
5EAW6H)		
Package Description	Marketing Start Date	Marketing End Date
10 in 1 CARTON	03/08/2022	
L g in 1 PATCH; Type 0: Not a Combination Product		
nformation		
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
part348	03/08/2022	
	4T6H12BN9U) DI2LOH54Z) (1000 MW) (UNII: 5XB3A63Y52) 5EAW6H) Package Description 40 in 1 CARTON L g in 1 PATCH; Type 0: Not a Combination Product Iformation Application Number or Monograph Citation	4T6H12BN9U) D12L0H54Z) (1000 MW) (UNII: 5XB3A63Y52) 5EAW6H) Marketing Start Date Package Description Marketing Start Date 40 in 1 CARTON L g in 1 PATCH; Type 0: Not a Combination Product

Labeler - Topco Associates LLC (006935977)

Revised: 7/2022

Topco Associates LLC