VALTRUM SOOTHING TOPICAL ANALGESIC- camphor (synthetic), menthol, methyl salicylate ointment

Laboratorios Quantium 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.

Valtrum Soothing Topical Analgesic Ointment

Drug Facts

Active Ingredients

Camphor 2,5%

Menthol 2,5%

Methyl Salicilate 10%

Purpose

Pain Relieving

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with •Rheumatism •Muscle strain •Sprains •Bruises •Neck and Shoulder Stiffness

Warnings

• For External use only

When using this product

- Use only as directed.
- Do not get into eyes or on mucous membranes.
- Do not apply to wounds or damaged skin.
- Do not bandage tightly.

Do Not Use

- in children under 8 years of age.
- if pregnant or nursing.
- with heating pad or apply external heat.

Flammable:

• Keep away from heat and flame.

Stop use and ask doctor if

- Skin redness or excessive irritation of the skin occurs
- Condition worsens
- Symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out of the reach of children

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

Directions:

Apply directly to the affected area. Do not rub or massage. The skin will absorb quickly. Apply every 6 hours. Do not use more than 4 times daily

Inactive ingredients:

Alcohol, Arnica Plant Extract, Carbopol, Cat's Claw Plant Extract, Devil's Claw Plant Extract, Chuchuhuasi Plant Extract, Glucosamine, Trietanolamina, water.

Other Information:

For your protection, this bottle has an imprinted seal around the neck. Do not use if tamper evident seal is missing, broken or destroyed.

Package Labeling:



VALTRUM SOOTHING TOPICAL ANALGESIC

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Product Information	oduct Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75849-300		
Route of Administration	TOPICAL				

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	25 mg in 1 g		
MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	25 mg in 1 g		
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	100 mg in 1 g		

Inactive Ingredients	
Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
HARPAGO PHYTUM PRO CUMBENS RO OT (UNII: 10 YM338 E89)	
GLUCO SAMINE (UNII: N08U5BOQ1K)	
TROLAMINE (UNII: 903K93S3TK)	
WATER (UNII: 059QF0KO0R)	

	Packaging				
:	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:75849-300-00	1 in 1 CARTON	11/12/20 15		
	1	90 g in 1 BOTTLE; 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	11/12/2015		

Labeler - Laboratorios Quantium LLC (027101451)

Revised: 9/2020 Laboratorios Quantium LLC