VALTRUM ANALGESIC- camphor (synthetic), menthol, menthyl salicylate gel 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 Topical Analgesic Gel

Drug Facts

Active Ingredients

Camphor 3% Menthol 3% Menthyl salicilate 10%

Purpose

Topical analgesic

Uses

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

• Simple Backache • Arthritis • Strains • Bruises • Sprains

Warnings

For external use only

- Avoid contact with eyes and mucous membranes
- Do not use otherwise than as directed.

Caution: Discontinue use if excessive irritation of the skin develops.

When using this product:

- Do not bandage tightly
- Do not apply to wounds or damaged skin.

Stop use and ask a doctor if:

- Conditions worsens
- Symptoms persist for more than 7 days or 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 right away.

Directions

Adults and Children 18 years of age and older: Apply to affected area not more than 3 to 4 times daily. Children under 18 years of age: Consult a doctor.

Other information

- Store in a cool dry place away from direct sunlight
- Keep lid tightly closed

Inactive Ingredients:

Arnica Montana Extract, Carbopol 940, Cat's Claw Extract, Chuchuhuasi Extract, Devil's Claw Extract, Glucosamine Sulfate, Isopropil Alcohol, Peg 40 Castor Oil, Purified Water, Triethanolamine.

Package Labeling:



quantiumlab@gmail.com 302-214-9718 / 786-250-8995

SYIEE , 33 - IMAIM ольитиммер різтківитока, іис EXCLUSIVELY DISTRIBUTED FOR USA BY:

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Product Information

Product Type HUMAN OTC DRUG **Item Code (Source)** NDC:75849-312

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC UNII:5TJD82A1ET)) - CAMPHOR (SYNTHETIC)	30 mg in 1 g
MENTUOL (UNIII, 17710FID2A) (MENTUOL LINIII, 17710FID2A)	MENTUOL	30 mg

MENTHYL SALICYLATE, (+/-)- (UNII: 43XOA705ZD) (SALICYLIC ACID - MENTHYL SALICYLUMII: 0414PZ4LPZ) (+/-)-	LATE, 100 mg

Inactive Ingredients	
Ingredient Name	Strength
CAT'S CLAW (UNII: 9060PRM18Q)	
MAYTENUS KRUKOVII BARK (UNII: K50SD0PDVR)	
ARNICA MONTANA WHOLE (UNII: O80TY208ZW)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 903K93S3TK)	
HARPAGOPHYTUM PROCUMBENS ROOT (UNII: 10YM338E89)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:75849-312- 03	90 g in 1 TUBE; Type 0: Not a Combination Product	07/15/2021	

Marketing Information			
Marketing Application Number or Monogra Category Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/15/2021	

Labeler - Laboratorios Quantium LLC (027101451)

Establishment			
Name	Address	ID/FEI	Business Operations
GADAL Laboratories, Inc		841305639	manufacture(75849-312) , label(75849-312) , pack(75849-312)

Revised: 8/2021 Laboratorios Quantium LLC