VALTRUM AEROBIC SPORTS- salicylic acid menthol camphor (natural) 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.

ACTIVE INGREDIENTS

Active Ingredients	Purpose
Methyl Salicylate 10%	Topical Analgesic
Menthol 3%	Topical Analgesic
Camphor 3%	Topical Analgesic

INACTIVE INGREDIENT

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

KEEP OUT OF REACH OF CHILDREN

WARNINGS

For the 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 use as directed.

- 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.

DOSAGE & ADMINISTRATION

Adults and children 18 years of age and older: Spray a thin layer over the affected area not more than 3 to 4 times daily.

Children under 18 years of age: Consult a doctor.

PURPOSE

For temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, sprains.

Valtrum Aerobic Sports

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Drug Facts

Active Ingredients Purpose
Camphor 3% Topical analgesic
Menthol 3 % Topical analgesic
Menthyl salicilate 10% 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: Spray a thin layer over the affected area not more than 3 to 4 times daily.

Children under 18 years of age: Consult a doctor

Other information

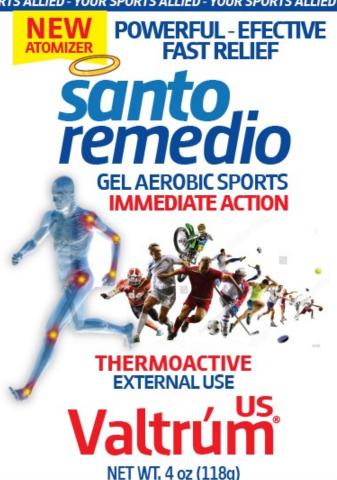
■Store in a cool dry place away from direct sunlight ■Keep lid tightly closed

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.



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VALTRUM AEROBIC SPORTS

salicylic acid menthol camphor (natural) gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:75849-304

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	10 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3 g in 100 g
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	3 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
ARNICA MONTANA (UNII: O80TY208ZW)		
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)		
CAT'S CLAW (UNII: 9060 PRM18 Q)		
MAYTENUS KRUKOVII BARK (UNII: K50SD0PDVR)		
HARPAGOPHYTUM PROCUMBENS ROOT (UNII: 10 YM338 E89)		
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		
PEG-40 SORBITAN DIISOSTEARATE (UNII: JL4CCU7I1G)		
TROLAMINE (UNII: 903K93S3TK)		
WATER (UNII: 059QF0KO0R)		

Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NI	OC:75849-304-04	118 g in 1 TUBE; Type 0: Not a Combination Product	0 3/0 1/20 19	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	03/01/2019		

Labeler - Laboratorios Quantium LLC (027101451)

Establishment				
Name	Address	ID/FEI	Business Operations	
GADAL Laboratories, Inc		841305639	MANUFACTURE(75849-304)	

Revised: 3/2019 LABORATORIOS QUANTIUM LLC