XOTEN-C - methyl salicylate, menthol, capsaicin lotion Living Well Pharmacy 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.

Drug Facts

Active ingredients

Methyl salicylate 20% Menthol USP 10% Capsaicin 0.002%

Purpose

Topical analgesic

Use

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

- simple backache
- arthritis
- sprains
- strains
- bruises

Warnings

For external use only.

Do not use

- on wounds
- damaged, broken, or irritated skin
- with a heating pad
- immediately before or after taking a bath or shower

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days
- skin irritation occurs

When using this product

- avoid contact with lips, eyes, nose and any mucous membranes at all times
- do not bandage tightly

Keep out of reach of children.

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

Directions

- use only as directed
- Wash hands thoroughly after use to avoid spreading lotion to the eyes or other sensitive areas of the body
- if applying lotion to the hands, wait 30 minutes before washing hands
- Adults and children 12 years of age and older:
 - apply to affected area not more than 3-4 times daily
- Children under 12 years of age:
 - do not use
 - consult a doctor

Other information

■ Store at room temperature

Inactive ingredients

D.I. Water, Ethylhexyl Palmitate, Cetearyl Alcohol, Glycerin, Arnica Extract, Aloe Babadensis (Aloe Vera) Leaf Extract, Vitamin E Acetate, Carbomer, Triethanolamine, Phenoxyethanol and Methyldibrome Glutaronitrile

Principal Display Panel – Bottle Label

64038-094401

XOTEN-C

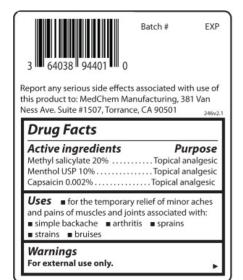
Pain Relief

Beneficial for relieving muscle pain and swelling

Manufactured for: **Net Wt. 4 oz**MedChem Manufacturing **(113.4 g)**Transport **(24.00501**

Torrance, CA 90501





Do not use no wounds damaged, broken, or irritated skin with a heating pad immediately before or after taking a bath or shower Stop use and ask a doctor if condition worsens symptoms persist for more than 7 days or clear up and occur again within a few days skin irritation occurs When using this product avoid contact with lips, eyes, nose, and any mucous membranes at all times do not bandage tightly Keep out of reach of children. If swallowed get medical help or contact a Poison Control

Center right away.

■ use only as directed

Directions

Drug Facts (continued)

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XOTEN-C

methyl salicylate, menthol, capsaicin lotion

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:64038-944 Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Methyl salicylate (UNII: LAV5U5022Y) (Methyl salicylate - UNII:LAV5U5022Y)	Methyl salicylate	20 g in 100 g		
Menthol (UNII: L7T10 EIP3A) (Menthol - UNII:L7T10 EIP3A)	Menthol	10 g in 100 g		
Capsaicin (UNII: S07O44R1ZM) (Capsaicin - UNII:S07O44R1ZM)	Capsaicin	0.002 g in 100 g		

Inactive Ingredients	
Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Ethylhexyl Palmitate (UNII: 2865993309)	

CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
Glycerin (UNII: PDC6A3C0OX)	
ARNICA MONTANA (UNII: O80TY208ZW)	
Aloe Vera Leaf (UNII: ZY8 1Z8 3H0 X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
METHYLDIBROMO GLUTARONITRILE (UNII: YX089CPS05)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:64038-944-01	113.4 g in 1 BOTTLE				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part348	08/01/2011			

Labeler - Living Well Pharmacy Inc. (070488957)

Revised: 7/2011 Living Well Pharmacy Inc.