

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 Methyldibromide Glutaronitrile

Principal Display Panel – Bottle Label

64038-094401

XOTEN-C

Pain Relief

Lotion

**Beneficial for relieving
muscle pain and swelling**

Manufactured for: **Net Wt. 4 oz**
MedChem Manufacturing (**113.4 g**)
Torrance, CA 90501

NDC 64038-944-01

XOTEN-C

Pain Relief Lotion

Beneficial for relieving muscle pain and swelling

Manufactured for: **MedChem Manufacturing**
Torrance, CA 90501

Net Wt. 4 oz
(113.4 g)



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Batch # EXP

Report any serious side effects associated with use of this product to: MedChem Manufacturing, 381 Van Ness Ave. Suite #1507, Torrance, CA 90501 246v2.1

Drug Facts

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Menthol USP 10%	Topical analgesic
Capsaicin 0.002%	Topical analgesic

Uses ■ for the temporary relief of minor aches and pains of muscles and joints associated with:
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Drug Facts (continued)

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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.

Directions
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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: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	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: 059QF0K00R)			
Ethylhexyl Palmitate (UNII: 2865993309)			

CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
Glycerin (UNII: PDC6A3C0OX)	
ARNICA MONTANA (UNII: O80TY208ZW)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
METHYLDIBROMO GLUTARONITRILE (UNII: YX089CPS05)	

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.