

DUANE READE HOT AND COLD BALM- methyl salicylate and menthol salve

Duane Reade

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 Purpose

Methyl Salicylate 29% ...Topical Analgesic

Menthol 7.6%Topical Analgesic

Uses

temporarily relieves the minor pains associated with:

- arthritis
- cramps
- bruises
- sprains
- backache

Warnings

For external use only

Allergy alert:

If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

When using this product

- use only as directed
- avoid contact with eyes or mucous membranes
- do not bandage tightly or with a heating pad
- do not apply to wounds or damaged skin

Stop use and ask a doctor if

- condition worsens
- redness is present
- irritation develops
- 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 over 12 years :

- apply generously to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but no more than 4 times daily

children under 12 years: ask a doctor.

Inactive ingredients

petrolatum, paraffin

Placeholder text

Top

NDC# 24488-023-02

UNIQUELY NY **DR** SINCE 1960

hot and cold balm

extra strength

relief of minor muscle & joint aches due to:
strains, sprains, bruises, backache, and arthritis

NET WT 3.5 OZ (104 mL)

Drug Facts

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Menthol 7.6%	Topical Analgesic

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When using this product ■ use only as directed ■ avoid contact with eyes or mucous membranes ■ do not bandage tightly or use with a heating pad ■ do not apply to wounds or damaged skin

Stop use and ask a doctor if ■ condition

Drug Facts (continue)

worsens ■ redness is present ■ irritation develops ■ symptoms persist for more than 7 days or clear up and occur again within a few days

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Inactive ingredients petrolatum, paraffin

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Item#
51066-4

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1.875" x 6.375" (conicalized)

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DUANE READE HOT AND COLD BALM

methyl salicylate and menthol salve

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24488-023
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (METHYL SALICYLATE - UNII:LAV5U5022Y)	METHYL SALICYLATE	30.16 mL in 104 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	7.90 mL in 104 mL

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
PARAFFIN (UNII: I9O0E3H2ZE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24488-023-02	104 mL in 1 CANISTER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/28/2011	

Labeler - Duane Reade (961956229)

Registrant - Creations Garden Natural Products Inc. (961956229)

Establishment

Name	Address	ID/FEI	Business Operations
Creations Garden Natural Products Inc.		961956229	manufacture

Revised: 2/2011

Duane Reade