CAPSAICIN 0.075% CREAM- capsaicin cream ViolaCare, Inc.

Capsaicin 0.075% Cream

Drug facts

Active Ingredient Purpose

Capsaicin 0.075%......Topical Analgesic

Uses

Temporarily relieves minor aches and pains of muscles and joints due to:

- simple backache
- arthritis
- strains
- sprains

Warnings

For external use only. Read all warnings and directions before use. Test first on small area of the skin.

Do not use

- on wounds or damaged skin
- if you are allergic to capsaicum or chili peppers

When using this product

- you may experience a burning sensation. The intensity of this reaction varies among individuals and may be severe. With regular use, this sensation generally disappears after several days.
- avoid contact with eyes, lips, nose and mucous membranes
- do not tightly wrap or bandage the treated area
- do not apply heat to the treated area immediately before or after use

Stop use and ask doctor if

- condition worsens or does not improve after regular use
- severe burning persists or blistering occurs

Directions adults and children 18 years and older:

- apply a thin film of cream to the affected area and gently rub in until fully absorbed
- unless treating hands, wash hands thoroughly with soap and water immediately after application
- for best results, apply 3 to 4 times daily.

children under 18 years:ask a doctor

Other information

Store at 20° C-25° C (68° F-77° F); excursions permitted to 15° C-30° C (59° F-86° F). See USP Controlled Room Temperature.

Inactive Ingredients

aloe barbadensis leaf juice, cetyl alcohol, glyceryl stearate, mineral oil, PEG-100 stearate, peppermint oil, petrolatum, phenoxyethanol, propylene glycol, stearyl alcohol, water, xanthan gum

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Questions? Call 877-227-3137

PRINCIPAL DISPLAY PANEL

Capsaicin 0.075% Cream - NDC 85231-202-60 - Pain Relieving Cream - Topical Analgesic - 2.11 OZ (60g) Tube Label

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🛞 Caps	aicin 0.()75% Cream
Pain Re l ievin	a Cream	Topical Analgesic
Full Kellevin	goreann	Topical Analgesic
NDC: 85231-20	•	2.11 OZ (60g)
NDC: 85231-20 Drug Facts See carton for	2-60	
NDC: 85231-20 Drug Facts See carton for Active Ingredient	92-60 Full drug facts Purpose	2.11 OZ (60g) Questions? Call 877-227-3137
NDC: 85231-20 Drug Facts See carton for Active Ingredient Capsaicin 0.075%	2-60 <u>full drug facts</u> <u>Purpose</u> Topical Ana	2.11 OZ (60g) Questions? Call 877-227-3137
NDC: 85231-20 Drug Facts See carton for Active Ingredient Capsaicin 0.075% Uses Temporarily relieves minor aches	12-60 <i>full drug facts</i> <i>Purpose</i> Topical Ana and pains of muscles and joints d	2.11 OZ (60g) Questions? Call 877-227-3137 Igesic
NDC: 85231-20 Drug Facts See carton for Active Ingredient Capsaicin 0.075% Uses Temporarily relieves minor aches Warnings For external use only. Read	2-60 <i>full drug facts</i> <i>Purpose</i> Topical Ana and pains of muscles and joints d all warnings and directions before	2.11 OZ (60g) Questions? Call 877-227-3137 Igesic ue to: • simple backache • arthritis • strains • sprains use. Test first on small area of the skin.
NDC: 85231-20 Drug Facts See carton for Active Ingredient Capsaicin 0.075% Uses Temporarily relieves minor aches Warnings For external use only. Read a Keep out of reach of children. If swa	2-60 full drug facts Purpose Topical Ana and pains of muscles and joints d all warnings and directions before illowed, get medical help or conta	2.11 OZ (60g) Questions? Call 877-227-3137 Igesic ue to: • simple backache • arthritis • strains • sprains use. Test first on small area of the skin.
NDC: 85231-20 Drug Facts See carton for Active Ingredient Capsaicin 0.075% Uses Temporarily relieves minor aches Warnings For external use only. Read a Keep out of reach of children. If swa	2-60 <i>full drug facts</i> <i>Purpose</i> Topical Ana and pains of muscles and joints d all warnings and directions before illowed, get medical help or conta is leaf juice, cetyl alcohol, glyceryl	2.11 OZ (60g) Questions? Call 877-227-3137 Igesic ue to: • simple backache • arthritis • strains • sprains use. Test first on small area of the skin. ct a Poison Control Center right away. stearate, mineral oil, PEG-100 stearate, peppermint oil,

Capsaicin 0.075% Cream - NDC 85231-202-60 - Pain Relieving Cream - Topical Analgesic - 2.11 OZ (60g) Carton Label



Manufactured For:

ViolaCare, Inc.

Parsippany, New Jersey, 07054

CAPSAICIN 0.075% CREAM							
capsaicin cream							
Product Information							
Product Type	HUMAN OTC DRUG	Item Coo	le (Source)	NDC:85231-202			
Route of Administration	TOPICAL						
Active Ingredient/Active Moiety							
Ingredi	ent Name		Basis of Strengt	h Strength			
CAPSAICIN (UNII: S07044R1ZM) (0	CAPSAICIN - UNII:S07044R1	ZM)	CAPSAICIN	0.075 g in 100 g			
Inactive Ingredients							
mactive ingredients							
	Ingredient Name			Strength			
ALOE VERA LEAF JUICE (UNII: RUI							
CETYL ALCOHOL (UNII: 936JST6JC	N)						
GLYCERYL STEARATE (UNII: 2300	U9XXE4)						

	MINERAL OIL (UNII: T5L8T28FGP)								
	PEG-100 STEARATE (UNII: YD01N1999R)								
PEPPERMINT OIL (UNII: AV092KU4JH)									
PETROLATUM (UNII: 4T6H12BN9U)									
PHENOXYETHANOL (UNII: HIE492ZZ3T)									
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)									
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)									
W	ATER (UNII: 059Q	F0KO0R)							
XA	ANTHAN GUM (UN	II: TTV12P4NEE)							
Packaging Marketing Start Marketing End # Item Code Package Description Marketing Start Marketing End									
			Date	Date					
1	NDC:85231-202- 60	1 in 1 CARTON	Date 06/02/2025	Date					
1 1				Date					
1	60	1 in 1 CARTON 60 g in 1 TUBE; Type 0: Not a Combination		Date					

Category	Citation	Date
OTC Monograph Drug	M017	06/02/2025

Labeler - ViolaCare, Inc. (119452160)

Revised: 6/2025

ViolaCare, Inc.