

CAPSADYN- capsaicin cream

Chorda Pharma, Inc

Capsadyn

Topical analgesic

Capsaicin 0.25% as Capsaicin palmitate

For the temporary relief of minor aches and pains of muscles and joints associated with arthritis, muscle strains, sprains, bruises, related muscle injuries, and simple backache. Provides penetrating pain relief.

For external use only.

Do not apply to wounds and damaged skin.

When using this product use only as directed, temporary warming of skin may be experienced after application, avoid contact with eyes or mucous membranes, do not bandage tightly, do not expose the treated area to heat, and avoid activity that may cause perspiration.

Stop use and ask a doctor if condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days.

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

Adults and children 18 years of age and older:

apply to affected areas not more than 3-4 times daily, rub in the cream until completely absorbed, the amount used depends on the depth of the pain, typically provides pain relief without any noticeable warming or cooling, **wash hands thoroughly with soap and water after applying.**

Children under 18 years of age: consult a doctor.

Butyrospermum parkii (shea) butter, cetareth-20, cetyl alcohol, cocos nucifera (coconut) oil, ethylhexylglycerin, glycerin, glyceryl stearate, helianthus annuus (sunflower) seed oil, myristyl myristate, phenoxyethanol, polysorbate 20, stearic acid, water.

<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none">• adults and children 18 years of age and older:• apply to affected areas not more than 3-4 times daily• rub in the cream until completely absorbed• the amount used depends on the depth of the pain• typically provides pain relief without any noticeable warming or cooling• wash hands thoroughly with soap and water after applying• children under 18 years of age: consult a doctor <p>Inactive ingredients butyrospermum parkii (shea) butter, cetareth-20, cetyl alcohol, cocos nucifera (coconut) oil, ethylhexylglycerin, glycerin, glyceryl stearate, helianthus annuus (sunflower) seed oil, myristyl myristate, phenoxyethanol, polysorbate 20, stearic acid, water.</p> <p>Manufactured for: Chorda Pharma, Inc., Roanoke, Virginia To order, visit capsadyn.com or call 540-632-0008</p> 	<p>CAPSADYN™ Maximum Strength 0.25% Non-Burning Capsaicin Cream</p> <p>Safe And Effective Treatment Of Chronic Pain</p> <ul style="list-style-type: none">• Developed to treat joint, arthritis, and muscle pain without opioids• The only capsaicin cream that blocks pain without burning the skin• Long-lasting relief when used as directed• Capsaicin is recognized by the FDA as safe and effective for pain relief	<p>NDC 83009-169-01</p> <p>CAPSADYN™ Maximum Strength 0.25%</p> <p>Non-Burning Capsaicin Cream Deep Penetrating Pain Relief</p>  <p>chorda PHARMA Net Wt. 1 oz (28 g)</p>	<table border="1"><tr><td>Drug Facts</td><td></td></tr><tr><td>Active ingredient Capsaicin 0.25% as Capsaicin palmitate</td><td>Purpose Topical analgesic</td></tr><tr><td>Uses For the temporary relief of minor aches and pains of muscles and joints associated with arthritis, muscle strains, sprains, bruises, related muscle injuries, and simple backache • provides penetrating pain relief</td><td></td></tr><tr><td>Warnings For external use only. Do not apply • to wounds • to damaged skin</td><td></td></tr><tr><td>When using this product • use only as directed • temporary warming of skin may be experienced after application • avoid contact with eyes or mucous membranes • do not bandage tightly • do not expose the treated area to heat • avoid activity that may cause perspiration</td><td></td></tr><tr><td>Stop use and ask a doctor if • condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days</td><td></td></tr><tr><td>Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</td><td></td></tr></table>	Drug Facts		Active ingredient Capsaicin 0.25% as Capsaicin palmitate	Purpose Topical analgesic	Uses For the temporary relief of minor aches and pains of muscles and joints associated with arthritis, muscle strains, sprains, bruises, related muscle injuries, and simple backache • provides penetrating pain relief		Warnings For external use only. Do not apply • to wounds • to damaged skin		When using this product • use only as directed • temporary warming of skin may be experienced after application • avoid contact with eyes or mucous membranes • do not bandage tightly • do not expose the treated area to heat • avoid activity that may cause perspiration		Stop use and ask a doctor if • condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days		Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83009-169	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)		CAPSAICIN	0.25 g in 100 g	
Inactive Ingredients				
Ingredient Name			Strength	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
COCONUT OIL (UNII: Q9L0O73W7L)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)				
SHEA BUTTER (UNII: K49155WL9Y)				
SUNFLOWER OIL (UNII: 3W1JG795YI)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83009-169-01	28 g in 1 JAR; Type 0: Not a Combination Product	10/13/2023	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017		10/13/2023	

Labeler - Chorda Pharma, Inc (099853035)

Registrant - Derma Care Research Labs, LLC (116817470)

Establishment

Name	Address	ID/FEI	Business Operations
Derma Care Research Labs, LLC		116817470	manufacture(83009-169)

