CVS CAPSAICIN - capsaicin cream CVS Pharmacy

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 ingredient

Purpose

Capsaicin 0.1%......Topical analgesic

Uses for the temporary relieves of minor aches and pains of muscles and joints associated with: - arthritis - simple backache - strains - bruises

Keep out of reach of children. If case of overdose or allergic reaction, seek medical attention or contact

a Poison Control Center right away.

Uses for the temporary relieves of minor aches and pains of muscles and joints associated with: - arthritis - simple backache - strains - bruises

Warnings

For external use only

When using this product

- use only as directed - do not apply to wounds, damaged, broken or irritated skin - avoid contact with the eyes or mucous membranes - a slight burning sensation may occur upon application, but generally disappears in several days - if severe burning occurs, discontinue use - do not expose the treated area to heat or direct sunlight - do not bandage - do not use with heating pad

Stop use and consult a dentist or doctor if:

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

- redness is present - irritation develops

Keep out of the reach of children.In case of overdose or allergic reaction, seek medical attention or contact a Poison Control Center right away.

If pregnant or breast feeding, ask a health professional before use.

Directions

Adults and children over 18 years

- apply to affected area

- Massage into the painful area until thoroughly absorbed
- Repeat as necessary, but no more than 3 to 4 times daily

- WASH HANDS WITH SOAP AND WATER AFTER APPLYING

Children 18 years and younger: ask a doctor.

Inactive Ingredients

purified water, petrolatum, cetyl alcohol glyceryl stearate, PEG-40 stearate, isopropyl myristate, sorbitol, PEG-2 stearate, benzyl alcohol



CVS CAPSAICIN capsaicin cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-622

Route	of Administratio	n O	RAL				
Active	e Ingredient/A	ctive Moiet	y				
		Ingred	ient Name		Basis of Stre	ength	Strength
CAPSA	ICIN (UNII: S0704	4R1ZM) (CAPSA	ICIN - UNII:S07044R12	ZM)	CAPSAICIN 7		75 mg in 1 g
Inactiv	ve Ingredients	5					
Ingredient Name				Strength			
DIGLYCOL STEARATE (UNII: 94YQ11Y95F)							
PETROLATUM (UNII: 4T6H12BN9U)							
POLYO	OXYL 40 STEARA	TE (UNII: 13A4J	4NH9I)				
BENZY	LALCOHOL (UN	II: LKG8494WB	H)				
CETYL	ALCOHOL (UNII:	936JST6JCN)					
SORBI	TOL (UNII: 506T6	0 A25R)					
ISOPRO	OPYL MYRISTAT	E (UNII: 0 RE8K	4LNJS)				
WATER (UNII: 059QF0KO0R)							
Packa	ging						
#	Item Code	Packa	ge Description	Marketing Star	t Date M	/larketing	g End Date
1 NDC:	59779-622-65	1 in 1 CART					-
1		42.5 g in 1 T	UBE				

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	07/08/2010	

Labeler - CVS Pharmacy (062312574)

Registrant - Pharma Pac, LLC (140807475)

Establishment				
Name	Address	ID/FEI	Business Operations	
Pharma Pac, LLC		140807475	manufacture	

Revised: 7/2010

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