CAPSAICIN- capsaicin 0.15% liquid Top Care

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 0.15%......Topical analgesic

Uses

Temporarily relieves minor aches and pains of muscles and joints associated with: • arthritis • simple backache • strains • sprains • bruises

Warnings

For external use only

When using this product • Use only as directed • Do not bandage tightly

- Do not use with a heating pad
- Avoid contact with eyes and mucous membranes
- Do not apply to wounds, damaged, broken or irritated skin
- A transient burning sensation may occur upon application but generally disappears in several days
- If severe burning sensation occurs, discontinue use immediately and read package insert for important information
- Do not expose the area treated with product to heat or direct sunlight

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

Flammable Keep away from fire or flame

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

Directions

Adults and children over 18 years: • Apply to affected area

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

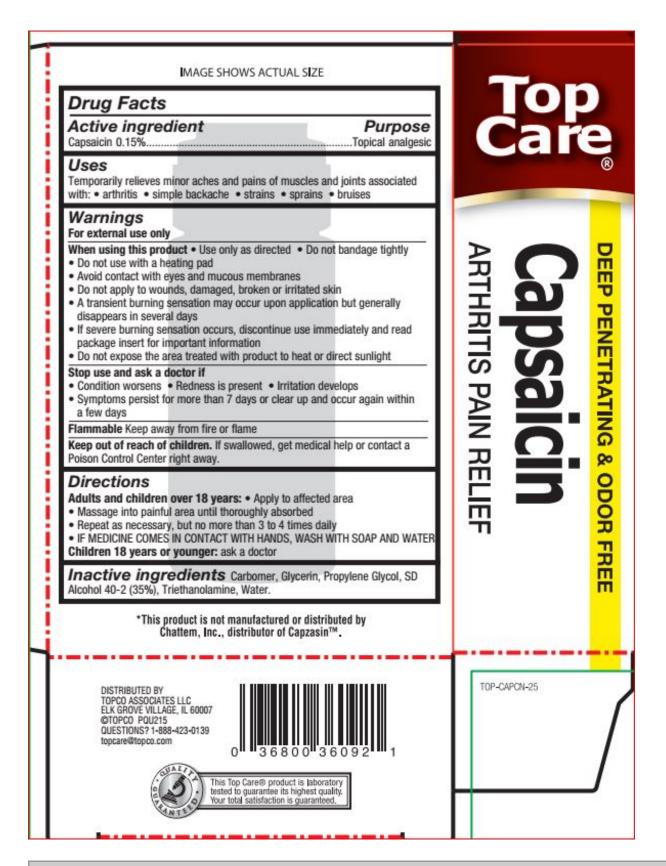
• IF MEDICINE COMES IN CONTACT WITH HANDS, WASH WITH SOAP AND WATER

Children 18 years or younger: ask a doctor

Inactive ingredients

Carbomer, Glycerin, Propylene Glycol, SD Alcohol 40-2 (35%), Triethanolamine, Water.





CAPSAICIN

capsaicin 0.15% liquid

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-729		
Route of Administration	TOPICAL				

J	ctive Moiety						
	Ingredient Name	Basis of Strength	Strength				
Capsaicin (UNII: S07O44)	R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	Capsaicin	0.15 g in 100 mL				
Inactive Ingredients	S						
Ingredient Name							
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)							
Glycerin (UNII: PDC6A3C0OX)							
Propylene Glycol (UNII: 6DC9Q167V3)							
Alcohol (UNII: 3K9958V90M)							
TROLAMINE (UNII: 903K	(93S3TK)						
Water (UNII: 059QF0KO0R)							
Packaging							
00	Package Description	Marketing Start Date	Marketing End Dat				
# Item Code	Package Description) mL in 1 TUBE; Type 0: Not a Combination Product	0	Marketing End Dat				
# Item Code	5	0	Marketing End Dat				
# Item Code	5	0	Marketing End Dat				
# Item Code 1 NDC:36800-729-01 30) mL in 1 TUBE; Type 0: Not a Combination Product	0	Marketing End Dat				
# Item Code 1 NDC:36800-729-01 30) mL in 1 TUBE; Type 0: Not a Combination Product	10/20/2011	Marketing End Data Marketing End Data				
1 NDC:36800-729-01 30 Marketing Information 1) mL in 1 TUBE; Type 0: Not a Combination Product	10/20/2011					

Labeler - Top Care (006935977)

Registrant - Product Quest Mfg (927768135)

Establishment					
Name	Address	ID/FEI	Business Operations		
Product Quest Mfg		927768135	manufacture(36800-729), label(36800-729)		

Revised: 7/2018

Top Care