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

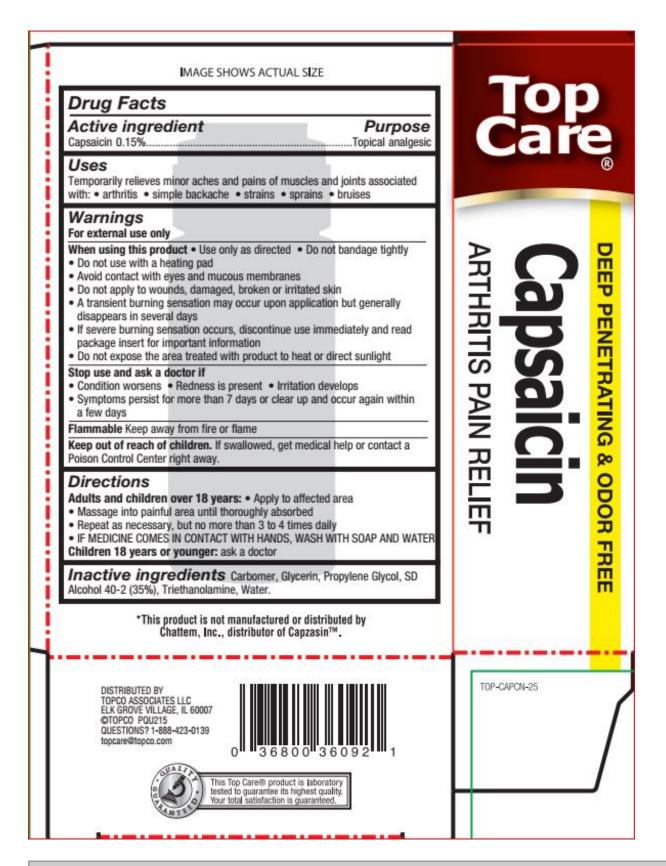
• IF MEDICINE COMES IN CONTACT WITH HANDS, WASH WITH SOAP AND WATER

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