

CAPSAICIN CREAM- capsaicin cream
Trifecta Pharmaceuticals USA LLC

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.

Globe Capsaicin Cream

Drug Facts

Active Ingredient

Capsaicin 0.1%

Purpose

Topical Analgesic

Warnings

For external use only: TEST FIRST ON SMALL AREA OF SKIN.

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 after 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
- Do not use at the same time as other topical analgesics

Stop Use and Ask Doctor

Stop Use and Ask 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
- You experience signs of skin injury such as pain, swelling or blistering.

Keep Out of the Reach of Children

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

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with:

- Arthritis
- Simple Backache
- Strains
- Sprains
- Bruises

If Pregnant or Breast Feeding

Ask a doctor 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 not 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

Aloe barbadensis leaf juice, Cetostearyl alcohol, Ethylparaben, Glycerin, Glyceryl monostearate, Mineral Oil, Petrolatum, Purified Water, Polyoxyethylene Lauryl Ether, Stearic Acid

Other Information

Store at room temperature 15°-30°F (59°-86°F)

This product is not manufactured or distributed by Chattem, distributor of Capzaicin-HP arthritis pain relief.

Questions

Questions or Comments

Please call Toll Free 1-888-296-9067

Other Information

Distributed by

Trifecta Pharmaceuticals USA

101 NE Third Avenue, Suite 1500

Fort Lauderdale, FL 33301

www.trifecta-pharma.com

OUTSIDE BOX

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Fort Lauderdale, FL 33301 USA
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DRUG FACTS

Active ingredient	Purpose
Capsaicin 0.1%.....	Topical Analgesic

Uses

- For the temporary relief of minor aches and pains of muscles and joints associated with:
- arthritis ■ simple backache ■ strains
- sprains ■ bruises

Warnings

For external use only
TEST FIRST ON SMALL AREA OF SKIN.

When using this product

- use only as directed • do not apply to wounds, damaged, broken or irritated skin • do not use if you are allergic to capsicum or chili peppers
- 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 • do not use at the same time as other topical analgesics

Stop use and ask a 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 • you experience signs of skin injury such as pain, swelling, or blistering

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

If pregnant or breast-feeding, ask a doctor before use.

Directions

Adults and children under 18 years:

- Apply to affected area • Massage into the painful area until thoroughly absorbed • Repeat as necessary, but not more than 3 to 4 times daily
- Wash hands with soap and water after applying

Children 18 years and younger: ask a doctor

Other Information

Store at room temperature 15°- 30°C (59°- 86°F)

Inactive Ingredients
Aloe barbadensis leaf juice, Cetostearyl alcohol, Ethylparaben, Glycerin, Glucosyl monostearate,



HIGH POTENCY PAIN RELIEF CREAM

Capsaicin

0.1%



NDC: 69396-103-02



Capsaicin

0.1%

HIGH POTENCY PAIN RELIEF CREAM

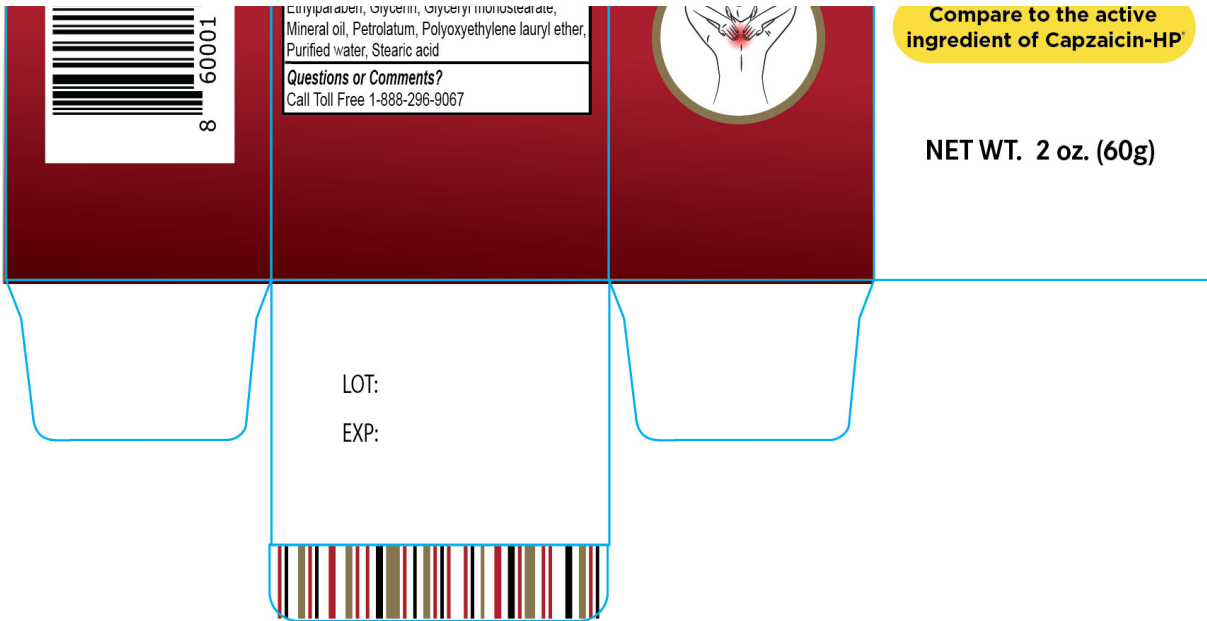
Deep Penetrating Relief from:
ARTHRITIS PAIN
MUSCLE & JOINT PAIN
BACK PAIN









INNER TUBE

NDC: 69396-103-02

Capsaicin 0.1%

HIGH POTENCY
PAIN RELIEF
CREAM

Deep Penetrating
Relief from:
ARTHRITIS PAIN
MUSCLE & JOINT PAIN
BACK PAIN

Compare to the active
ingredient of Capzaicin-HP

NET WT. 2 oz. (60g)

DRUG FACTS	
Active ingredients	Purpose
Capsaicin 0.1%.....	Topical Analgesic
Use	
<ul style="list-style-type: none"> ■ For the temporary relief of minor aches and pains of muscles and joints associated with ■ arthritis ■ simple backache ■ strains ■ sprains ■ bruises 	
Warnings	
For external use only. TEST FIRST ON SMALL AREA OF SKIN When using this product <ul style="list-style-type: none"> ■ 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 ■ do not use at the same time as other topical analgesics 	
Stop use and ask a doctor if <ul style="list-style-type: none"> ■ condition worsens ■ symptoms persist for more than 7 days or clear up and occur within a few days ■ redness is present ■ irritation develops ■ you experience signs of skin injury such as pain, swelling or blistering Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away. If pregnant or breast-feeding, ask a doctor before use.	
Directions	
Adults and children under 18 years <ul style="list-style-type: none"> ■ apply to affected area ■ Massage into the painful area until thoroughly absorbed ■ Repeat as necessary, but not 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	
Aloe barbadensis leaf juice, Cetostearyl alcohol, Ethylparaben, Glycerin, Glyceryl monostearate, Mineral oil, Petrolatum, Polyoxyethylene lauryl ether, Purified water, Stearic acid	
Questions or Comments?	
Call Toll Free 1-888-296-9067	

*This product is not manufactured or distributed by Chatterm, distributor of Capzaicin-HP[®] Arthritis Pain Relief.

Distributed by:
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 Ft. Lauderdale, FL 33301 USA
www.trifecta-pharma.com

CAPSAICIN CREAM

capsaicin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
LAURETH-23 (UNII: N72LMW566G)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ETHYLPARABEN (UNII: 14255EXE39)	
MINERAL OIL (UNII: T5L8T28FGP)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-103-02	1 in 1 BOX	05/14/2022	
1		60 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/14/2022	

