

CAPSAICIN CREAM- capsaicin cream
Trifecta Pharmaceuticals USA LLC

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



← HIGH POTENCY PAIN RELIEF CREAM
0.1% Capsaicin



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 Capsaicin-HP

NET WT. 2 oz. (60g)

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 capsaicin 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

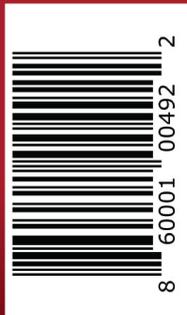
Aloe barbadensis leaf juice, Cetostearyl alcohol, Ethylparaben, Glycerin, Glyceryl monostearate, Mineral oil, Petrolatum, Polyoxyethylene lauryl ether, Purified water, Stearic acid

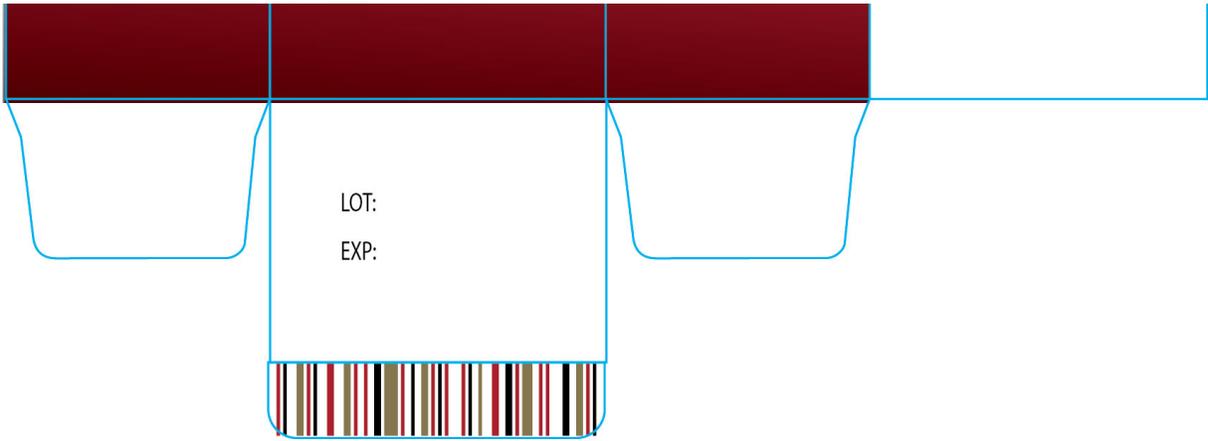
Questions or Comments?

Call Toll Free 1-888-296-9067



Distributed by:
Trifecta Pharmaceuticals USA
101 NE Third Avenue, Suite 1500
Fort Lauderdale, FL 33301 USA
www.trifecta-pharma.com





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:
Trifecta Pharmaceuticals USA*
 101 NE Third Avenue, Suite 1500
 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 Drug	M017	05/14/2022	

Labeler - Trifecta Pharmaceuticals USA LLC (079424163)