BRONSON SOOTHE PAIN RELIEF- capsaicin cream BRONSON NUTRITIONALS, LLC

BRONSON SOOTHE CREAM Pain Relief Cream

Drug Facts

ACTIVE INGREDIENT

Capsaicin 0.025%

PURPOSE

External Analgesic

USES:

For temporary relief of minor aches and pains of the muscles and joints associted with simple backache, arthritis, strains, bruises and sprains.

WARNINGS

- For external use only.
- Avoid contact with eyes.
- Do not apply to open wounds or damaged skin.
- If symtoms persist for more than seven days, discontinue use and consult physician.

Keep out of reach of children.

- If swallowed, contact physician.
- Do not bandage tightly .
- If pregnant or breast feeding, contact physician prior to use.

DIRECTIONS:

Apply directly to affected area. Do not use more than four times per day.

INACTIVE INGREDIENTS:

Aloe barbadensis (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arnica montana Flower Extract, Ascorbyl Palmitate (Vitamin C), C13-14 Isoparaffin, Cetyl Alcohol, Chamomilla recutita (Chamomile) Extract, Diazolidinyl Urea, Emu Oil, Hamamelis virginiana (Witch Hazel) Distillate, Isopropyl Alcohol, Isopropyl Myristate, Lamium album (White Nettle) Extract, Laureth-7, Menthol, Methyl Paraben, Methylsulfonylmethane (MSM), Parfum (Fragrance), PEG-8, Polyacrylamide, Propyl Paraben, Propylene Glycol, Sorbitol, Tocopheryl Acetate (Vitamin E).

OTHER INFORMATION:

- Store at room temperature.
- Protect from light.

Package Labeling:59ml



Package Labeling:118ml



No. 614

AND SOOTHE ACHING JOHNTS Area

- Deep penetrating relief right to the source
- · Powerful cooling cream, lasts for hours
- · Works on contact

SOOTHE CREAM*

Net Contents 4 fl. oz. (118 mL)

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OTHER INFORMATION: Store at room temperature.

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* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.



Lindon, UT 84042 Made in USA For Customer Information Call 1-800-235-3200

614



REF 1014

BRONSON SOOTHE PAIN RELIEF

capsaicin cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:83158-387

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength
ı	CAPSAICIN (UNII: S07044R1ZM) (CAPSAICIN - UNII:S07044R1ZM)	CAPSAICIN	0.25 mg in 1 mL

Inactive Ingredients				
Inactive Ingredients Ingredient Name	Strength			
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
WATER (UNII: 059QF0KO0R)				
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)				
ASCORBYL PALMITATE (UNII: QN83US2B0N)				
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
CHAMOMILE (UNII: FGL3685T2X)				
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)				
EMU OIL (UNII: 344821WD61)				
WITCH HAZEL (UNII: 10114J0U34)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)				
LAMIUM ALBUM WHOLE (UNII: 046Y1357I6)				
LAURETH-7 (UNII: Z95S6G8201)				
MENTHOL (UNII: L7T10EIP3A)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
PROPYLPARABEN (UNII: Z8IX2SC10H)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SORBITOL (UNII: 506T60A25R)				
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				

F	Packaging					
#	tem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:83158-387- 02	59 mL in 1 TUBE; Type 0: Not a Combination Product	12/26/2022			
2	NDC:83158-387- 04	118 mL in 1 TUBE; Type 0: Not a Combination Product	12/26/2022			

Marketing In	Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M017	12/26/2022			

Labeler - BRONSON NUTRITIONALS, LLC (130393494)