

PAIN RELIEF CAFFEINE AND HEMP- caffeine (coffeinum) 6x, hemp extract (cannabis sativa) 2x spray

Green Earth Health Inc.

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

Drug Facts

Active Ingredients

Caffeine (Coffeinum) 6X (0.0018mg) HPUS
Hemp extract (Cannabis sativa) 2X (11.3 mg) HPUS

Reference: the Homeopathic Pharmacopoeia of the United States (HPUS)

Purpose

Analgesic
Anti-inflammatory

Indication:

Temporarily relieves pain associated with cystitis, headaches, neuropathy, and sciatica.

Warnings:

- Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.
- If symptoms persist or worsen, stop using this product and consult physician.
- Avoid contact with eyes. If product gets into eyes, flush with water, seek medical attention.
- If pregnant or breastfeeding or if diagnosed with psychiatric or mood disorder, seek medical advice before use.
- Keep out of reach of children.

Directions For Use:

- Do not use if tamperproof cover is missing
- Press down 4 times to prime the pump.
- Spray 2 times directly into the mouth or under the tongue.
- Start using 3 times per day. Use as needed thereafter to relieve discomfort.
- Allow several days for product to take maximum effect.

Other Information:

- Published clinical reports suggest that active ingredients may provide relief from other types of pain and inflammation.
- Cannabidiol in hemp extract may alter the metabolism of other drugs.

Inactive Ingredients:

Citric acid USP, flavoring, glycerin USP, potassium sorbate USP, purified water, sodium benzoate NF, vitamin C USP, xanthan gum NF.

Principal display panel



PAIN RELIEF CAFFEINE AND HEMP

caffeine (coffeinum) 6x, hemp extract (cannabis sativa) 2x spray

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:73002-321

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAFFEINE CITRATE (UNII: U26EO4675Q) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE CITRATE	6 [hp_X] in 1 mL
CANNABIS SATIVA SUBSP. SATIVA FLOWERING TOP (UNII: 8X454SZ22D) (CANNABIS SATIVA SUBSP. SATIVA FLOWERING TOP - UNII:8X454SZ22D)	CANNABIS SATIVA SUBSP. SATIVA FLOWERING TOP	2 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
SIRAITIA GROSVENORII FRUIT (UNII: NOU2FB51TW)	
TEA LEAF (UNII: GH42T47V24)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73002-321-01	28 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	12/19/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/19/2019	

Labeler - Green Earth Health Inc. (116983264)

Establishment

Name	Address	ID/FEI	Business Operations
Maitland Labs of Central Florida		080974960	manufacture(73002-321)

Establishment

Name	Address	ID/FEI	Business Operations
Organics Corporation of America DBA Ambix Laboratories		061061164	manufacture(73002-321)