

CHARLEY HORSE- arnica montana, cupric arsenite, copper, magnesium phosphate, dibasic trihydrate, and toxicodendron pubescens leaf cream

Concept Laboratories, 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.

Charley Horse™ Cream

Drug Facts

Active ingredients HPUS	Purpose
Arnica Montana 4X HPUS	Ascending leg pain
Cuprum ars. 10X HPUS	Cramps in calves
Cuprum met. 11X HPUS	Spasms, leg cramps
Mag. phos. 10X HPUS	Cramps in calves
Rhus Tox. 4X HPUS	Leg pain, cramps in calves

Uses

temporarily relieves muscle pains, spasms and cramps in calves, feet and legs. Night cramps & pain in lower limbs.

Warnings

If symptoms persist or worsen, discontinue use and consult a physician. If you are pregnant or nursing seek the advice of a doctor before using. **Keep out of reach of children.**

Directions

Apply liberally to affected area. Massage gently until completely absorbed. Repeat as needed.

Inactive ingredients

Caprylic/Capric/Triglyceride, Caprylyl Glycol, Cetyl Alcohol, Dimethicone, Glyceryl Monostearate, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Hexylene Glycol, Methyl Salicylate, Persea Gratissima (Avocado) Oil, Phenoxyethanol, Polyethylene, Potassium Sorbate, Sodium Acrylate/Sodium Acryloyl Dimethyl Taurate Copolymer, Sodium Polyacrylate, Water (Aqua).

Manufactured for: Concept Laboratories, Inc., Chicago, IL 60642 (USA)

www.conceptlabs.org

CL10043

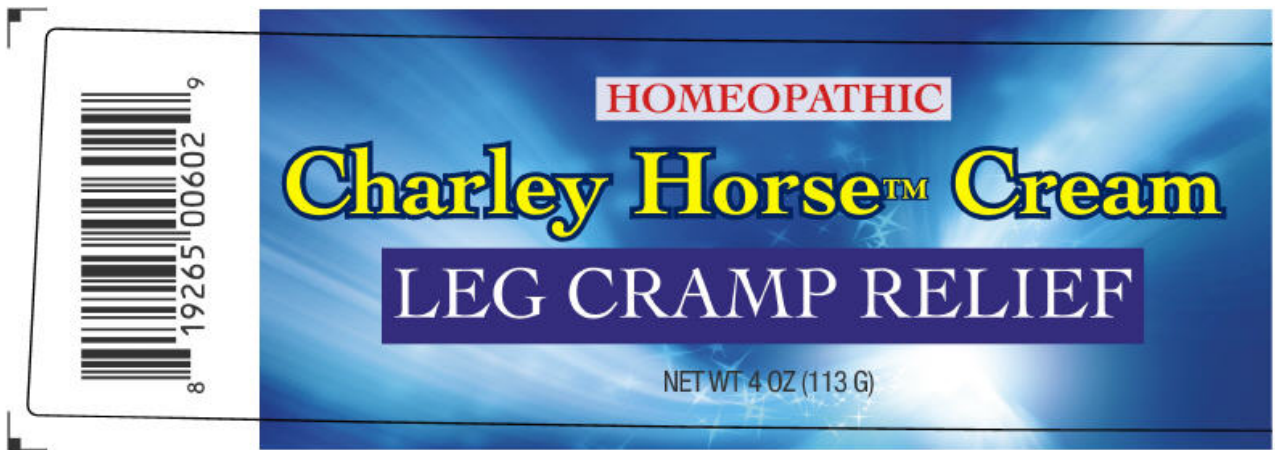
PRINCIPAL DISPLAY PANEL - 113 G Jar Label

HOMEOPATHIC

Charley Horse™ Cream

Leg Cramp Relief

NET WT 4 OZ (113 G)



Drug Facts

Active ingredients HPUS Purpose
 Arnica Montana 4X HPUS *Ascending leg pain*
 Cuprum ars. 10X HPUS *Cramps in calves*
 Cuprum met.11X HPUS *Spasms, leg cramps*
 Mag. phos. 10X HPUS *Cramps in calves*
 Rhus Tox. 4X HPUS *Leg pain, cramps in calves*

Uses temporarily relieves muscle pains, spasms and cramps in calves, feet and legs. Night cramps & pain in lower limbs.

Warnings If symptoms persist or worsen, discontinue use and consult a physician. If you are pregnant or nursing seek the advice of a doctor before using. **Keep out of reach of children.**

Directions Apply liberally to affected area. Massage gently until completely absorbed. Repeat as needed.

Inactive ingredients Caprylic/Capric Triglyceride, Caprylyl Glycol, Cetyl Alcohol, Dimethicone, Glycerol Monostearate, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Hexylene Glycol, Methyl Salicylate, Persea Gratissima (Avocado) Oil, Phenoxyethanol, Polyethylene, Potassium Sorbate, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Sodium Polyacrylate, Water (Aqua).

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← PRESS WEB DIRECTION

CHARLEY HORSE

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64058-159
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	4 [hp_X] in 113 g
CUPRIC ARSENITE (UNII: SK8L60BCSQ) (CUPRIC CATION - UNII:8CBV67279L, ARSENITE ION - UNII:N5509X556J)	CUPRIC ARSENITE	10 [hp_X] in 113 g
COPPER (UNII: 789U1901C5) (COPPER - UNII:789U1901C5)	COPPER	11 [hp_X] in 113 g
MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE (UNII: HF539G9L3Q) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE	10 [hp_X] in 113 g
TOXICODENDRON PUBESCENS LEAF (UNII: 61O182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:61O182RP7A)	TOXICODENDRON PUBESCENS LEAF	4 [hp_X] in 113 g

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Dimethicone (UNII: 92RU3N3Y1O)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Glycerin (UNII: PDC6A3C0OX)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
Hexylene Glycol (UNII: KEH0A3F75J)	
Methyl Salicylate (UNII: LAV5U5022Y)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
Potassium Sorbate (UNII: 1VPU26JZZ4)	
Sodium Acrylate (UNII: 7C98FKB43H)	
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64058-159-34	113 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED HOMEOPATHIC		01/29/2016	

Labeler - Concept Laboratories, Inc. (962282612)

Establishment

Name	Address	ID/FEI	Business Operations
Concept Laboratories, Inc.		962282612	LABEL(64058-159)

Establishment

Name	Address	ID/FEI	Business Operations
Filltech USA, LLC		965596435	MANUFACTURE(64058-159)

Revised: 2/2016

Concept Laboratories, Inc.