FIBROCANE RELIEF- symphytum officinale, capsicum annuum, ledum palustre, colchicum autumnale, rhododendron chrysanthum, ruta graveolens, gel Premier Bioceuticals LLC

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:

Symphytum officinale 3X, Capsicum annuum 6X, Ledum palustre 6X, Colchicum autumnale 12X, Rhododendron chrysanthum 12X, Ruta graveolens 12X.

INDICATIONS:

For temporary relief of minor symptoms of joint pain and inflammation.*

*These statements are based upon traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

WARNINGS:

For external use only.

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

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

When using this product do not get into eyes.

Stop use and call a doctor if condition worsens or symptoms last more than 7 days.

Consult a physician for use in children under 12 years of age.

KEEP OUT OF REACH OF CHILDREN:

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

DIRECTIONS:

Apply generously and rub thoroughly for 20-30 seconds over the affected area. Flexing and releasing the affected muscles and joints after applying this product may enhance its ability to help you. This process may be repeated several times a day.

INDICATIONS:

For temporary relief of minor symptoms of joint pain and inflammation.*

*These statements are based upon traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

INACTIVE INGREDIENTS:

Acrylates/C10-30 alkyl acrylate crosspolymer, Aloe barbadensis leaf juice, Arnica (flower), Ascorbic acid, Celery (seed), Comfrey leaf, Devil's Claw (root), Edate disodium (EDTA), Feverfew (leaf), Vitamin E, Oregano, PEG-33, PEG-8 Dimethicone, PEG-14, Phenoxyethanol, Capryly glycol, Sorbic acid, Poke (root), Potassium sorbate, Purified Water, Sodium hydroxide, Turmeric (root), White willow (bark)

QUESTIONS:

Distributed by Premier Bioceuticals LLC, P. O. BOX 78391 Indianapolis, IN 46278

PACKAGE LABEL DISPLAY:

Premier BIOCEUTICALS

NDC 57850-2000-1

Fibro Cane

RELIEF

For temporary relief of monor symptoms of joint pain and inflammation.

Homeopathic Gel

paraben-free

Ner wt. 2 oz. (57 g)

Indications:

For temporary relief of minor symptoms of joint pain and inflammation.*

Active ingredients:

Symphytum Officinale 3x, Capsicum Annuum 6x, Ledum Palustre 6x, Colchicum Autumnale 12x, Rhododendron Chrysanthum 12x, Ruta Graveolens 12x, Warnings:

For external use only. If pregnant or breast-teeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. When using this product do not get into eyes. Stop use and call a doctor if condition worsens or symptoms last more than 7 days. Consult a physician for use in children under 12 years of age.

Directions:

Apply generously and rub thoroughly for 20-30 seconds over the affected area. Flexing and releasing the affected muscles and joints after applying this product may enhance its ability to help you. This process may be repeated several times a day.

Inactive Ingredients:

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice. Arnica Flower, Ascorbic Acid. Celery Seed, Comfrey Leaf, Devil's Claw Root, Edetate Disodium, Feverfew Leaf, Mixed Tocopherols (soy), Natural Plant Extract, PEG-33 & PEG-8 Dimethicone & PEG-14, Phenoxyethanol & Caprylyl Glycol & Sorbic Acid, Poke Root, Potassium Sorbate, Purified Water, Sodium Hydroxide, Turmeric Root and White Willow Bark.

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unscented - non-greasy - petroleum free - no animal testing



NDC 57850-2000-1



For temporary relief of minor symptoms of joint pain and inflammation.

Homeopathic Gel

paraben-free

Net wt. 2 oz. (57 g)

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FIBROCANE RELIEF

symphytum officinale, capsicum annuum, ledum palustre, colchicum autumnale, rhododendron chrysanthum, ruta graveolens, gel

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:57850-2000 Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
COMFREY ROOT (UNII: M9 VVZ08EKQ) (COMFREY ROOT - UNII:M9 VVZ08EKQ)	COMFREY ROOT	3 [hp_X] in 1 g	
CAPSICUM (UNII: 00 UK7646 FG) (CAPSICUM - UNII:00 UK7646 FG)	CAPSICUM	6 [hp_X] in 1 g	
LEDUM PALUSTRE TWIG (UNII: 877L01IZ0P) (LEDUM PALUSTRE TWIG - UNII:877L01IZ0P)	LEDUM PALUSTRE TWIG	6 [hp_X] in 1 g	
COLCHICUM AUTUMNALE BULB (UNII: 993QHL78E6) (COLCHICUM AUTUMNALE BULB - UNII:993QHL78E6)	COLCHICUM AUTUMNALE BULB	12 [hp_X] in 1 g	

RHODODENDRON AUREUM LEAF (UNII: IV92NQJ73U) (RHODODENDRON AUREUM LEAF - UNII:IV92NQJ73U)	RHODODENDRON AUREUM LEAF	12 [hp_X] in 1 g
RUTA GRAVEOLENS FLOWERING TOP (UNII: N94C2U587S) (RUTA GRAVEOLENS FLOWERING TOP - UNII:N94C2U587S)	RUTA GRAVEOLENS FLOWERING TOP	12 [hp_X] in 1 g

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CELERY SEED (UNII: 1G1EAA320L)	
COMFREY LEAF (UNII: DG4F8T839X)	
HARPAGOPHYTUM PROCUMBENS ROOT (UNII: 10 YM338 E89)	
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)	
FEVERFEW (UNII: Z64FK7P217)	
.ALPHATOCOPHEROL (UNII: H4N855PNZ1)	
OREGANO (UNII: 0E5AT8T16U)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
PEG-8 DIMETHICONE (UNII: GIA7T764OD)	
POLYETHYLENE GLYCOL 700 (UNII: 762678 AC5R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
SORBIC ACID (UNII: X045WJ989B)	
PHYTOLACCA AMERICANA ROOT (UNII: 11E6 VI8 VEG)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDRO XIDE (UNII: 55X04QC32I)	
TURMERIC (UNII: 856 YO 1Z64F)	
SALIX ALBA BARK (UNII: 205MXS71H7)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57850-2000-1	57 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		06/17/2014	

Labeler - Premier Bioceuticals LLC (027714978)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address		Business Operations
Apotheca Company		844330915	manufacture(57850-2000), api manufacture(57850-2000), label(57850-2000), pack(57850-2000)

Revised: 6/2014 Premier Bioceuticals LLC