

MENOPAUSE RELIEF HOMEOPATHIC REMEDY- sepia cream
Homeocare 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.

PURPOSE

Relieves Menopausal Symptoms

ACTIVE INGREDIENTS

Dioscorea villosa
Cimicifuga racemosa
Sanguinaria Canadensis
Ignatia amara
Helonias dioica
Sepia
Ophorinum
Lachesis

INACTIVE INGREDIENTS

Avocado Oil
Caprylyl Glycol
Cetyl Alcohol
Dimethicone
Dimethyl Taurate Copolymer
Glycerin USP
Glyceryl Stearate
Hexylene Glycol
Phenoxyethanol
Polyethylene
Sodium Polyacrylate
Potassium Sorbate
Purified Water
Sodium Acrylate/Sodium Acryloyl
Sunflower Oil
Caprylic/Capric Triglyceride

KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact a poison control center right away.

QUESTIONS?

(877) 208-1555

DIRECTIONS

Rub a pea-sized amount on the underside of your wrist two (2) times a day for as long as you have symptoms.

DO NOT USE

In eyes, or on broken skin

If pregnant or breastfeeding, ask a health professional before use.

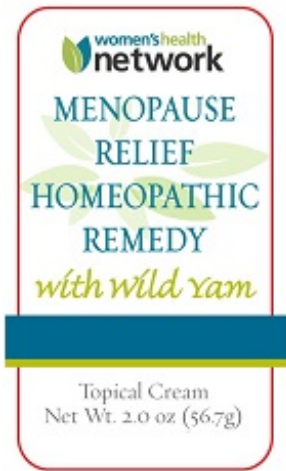
WARNINGS

For external use only

USES

Relieves menopausal symptoms

Hot flashes, night sweats, headaches



<p>Drug Facts (continued)</p> <p>Hexylene Glycol, Phenoxethanol, Polyethylene Glycol, Potassium Sorbate, Purified Water, Sodium Acrylate/Sodium Acrylate, Sunflower Oil</p> <p>Questions? (877) 208-1555</p> <p>Manufactured exclusively for: Women's Health Network P.O. Box 306 Portland, ME 04112</p> <p>831-1108</p>	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active Ingredients (per gram)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Cimicifuga racemosa 4X</td> <td>menopausal symptoms, menstrual irregularities</td> </tr> <tr> <td>Dioscorea villosa 1X</td> <td>menopausal distress, hot flashes, night sweats, night sweats, hot flashes, night sweats</td> </tr> <tr> <td>Helianthus divaricatus 6X</td> <td>loss of sexual desire, weakness, dyspareunia, menorrhagia, cramps</td> </tr> <tr> <td>Ignatia amara 12X</td> <td>irregular menses, cramp-like pain, menopause</td> </tr> <tr> <td>Lachesis 12X</td> <td>menopause troubles, hot flashes, headache</td> </tr> <tr> <td>Opuntia 12X</td> <td>menopause</td> </tr> </tbody> </table>	Active Ingredients (per gram)	Purpose	Cimicifuga racemosa 4X	menopausal symptoms, menstrual irregularities	Dioscorea villosa 1X	menopausal distress, hot flashes, night sweats, night sweats, hot flashes, night sweats	Helianthus divaricatus 6X	loss of sexual desire, weakness, dyspareunia, menorrhagia, cramps	Ignatia amara 12X	irregular menses, cramp-like pain, menopause	Lachesis 12X	menopause troubles, hot flashes, headache	Opuntia 12X	menopause
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<p>Drug Facts (continued)</p> <p>Sanguinaria canadensis 4X</p>	<p>Drug Facts (continued)</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions Rub a pea-sized amount on the underside of your wrist two (2) times a day for as long as you have symptoms.</p> <p>Inactive Ingredients Avocado Oil, Caprylic Glycol, Cetyl Alcohol, Dimethicone, Distearyl Tartrate Copolymer, Glycerin USP, Glyceryl Stearate, Caprylic/Capric Triglyceride</p>														

MENOPAUSE RELIEF HOMEOPATHIC REMEDY
sepia cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61727-054
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SANGUINARIA CANADENSIS ROOT (UNII: N9288CD508) (SANGUINARIA CANADENSIS ROOT - UNII:N9288CD508)	SANGUINARIA CANADENSIS ROOT	4 [hp_X] in 60 mL
STRYCHNOS IGNATII SEED (UNII: 1NM3M2487K) (STRYCHNOS IGNATII SEED - UNII:1NM3M2487K)	STRYCHNOS IGNATII SEED	12 [hp_X] in 60 mL
LACHESIS MUTA WHOLE (UNII: 6Y582I290C) (LACHESIS MUTA WHOLE - UNII:6Y582I290C)	LACHESIS MUTA WHOLE	12 [hp_X] in 60 mL
DIOSCOREA VILLOSA ROOT (UNII: IWY3IWX2G8) (DIOSCOREA VILLOSA ROOT - UNII:IWY3IWX2G8)	DIOSCOREA VILLOSA ROOT	1 [hp_X] in 60 mL
ACTAEA CIMICIFUGA ROOT (UNII: 65J267BAZT) (ACTAEA CIMICIFUGA ROOT - UNII:65J267BAZT)	ACTAEA CIMICIFUGA ROOT	4 [hp_X] in 60 mL
CHAMAELIRIUM LUTEUM ROOT (UNII: DQV54Y5H3U) (CHAMAELIRIUM LUTEUM ROOT - UNII:DQV54Y5H3U)	CHAMAELIRIUM LUTEUM ROOT	6 [hp_X] in 60 mL
SEPIA ESCULENTA WHOLE (UNII: 6ET21QP634) (SEPIA ESCULENTA WHOLE - UNII:6ET21QP634)	SEPIA ESCULENTA WHOLE	12 [hp_X] in 60 mL
SUS SCROFA OVARY (UNII: S7YTV04R8O) (SUS SCROFA OVARY - UNII:S7YTV04R8O)	SUS SCROFA OVARY	12 [hp_X] in 60 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
2,4-DIAMINO-5-METHYLPHENOXYETHANOL HYDROCHLORIDE (UNII: Z28JS1XMY2)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
POLYETHYLENE OXIDE 1000000 (UNII: HZ58M6D839)	
WATER (UNII: 059QF0K00R)	
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (4000000 MW) (UNII: 1DXE3F3OZX)	
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE 1000 (UNII: MCU2324216)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPAS AT 1%) (UNII: 86FQE96TZ4)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61727-054-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/30/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/30/2015	

Labeler - Homeocare Laboratories Inc. (088248828)

Establishment

Name	Address	ID/FEI	Business Operations
HomeoCare Laboratories Inc.		088248828	manufacture(61727-054)

Revised: 12/2015

Homeocare Laboratories Inc.