

MENSTRUAL - PMS - angelica sinensis radix, arsenicum alb., bryonia, caulophyllum, cimicifuga, cinchona, dioscorea, folliculinum, gelsemium, lachesis, lilium, lycopodium, millefolium, nux vom., pulsatilla, sabina, secale, sepia, thlaspi, viburnum op., zingiber, echinacea, valeriana liquid
Newton 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.

Menstrual - PMS

INDICATIONS & USAGE SECTION

Menstrual - PMS Formulated for associated symptoms such as irregularity, cramping, bloating, headache, cravings, emotional upsets and mood swings.

DOSAGE & ADMINISTRATION SECTION

Directions: ORAL USE ONLY - SHAKE WELL. Ages 12 and up, take 6 drops orally as needed or as directed by a healthcare professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

OTC - ACTIVE INGREDIENT SECTION

Angelica sinensis radix 15x, Arsenicum alb. 15x, Bryonia 15x, Caulophyllum 15x, Cimicifuga 15x, Cinchona 15x, Dioscorea 15x, Folliculinum 15x, Gelsemium 15x, Lachesis 15x, Lilium 15x, Lycopodium 15x, Millefolium 15x, Nux vom. 15x, Pulsatilla 15x, Sabina 15x, Secale 15x, Sepia 15x, Thlaspi 15x, Viburnum op. 15x, Zingiber 15x, Dioscorea 3x, Echinacea 3x, Valeriana 3x.

OTC - PURPOSE SECTION

Formulated for associated symptoms such as irregularity, cramping, bloating, headache, cravings, emotional upsets and mood swings.

INACTIVE INGREDIENT SECTION

Inactive Ingredients: USP Purified Water; USP Gluten-free, non-GMO, organic cane dispensing alcohol 20%.

QUESTIONS SECTION

www.newtonlabs.net Newton Laboratories, Inc. FDA Est # 1051203 - Conyers, GA 30012
Questions? 1.800.448.7256

WARNINGS SECTION

Warning: Do not use if tamper - evident seal is broken or missing. Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days. Keep out of reach of children.

OTC - PREGNANCY OR BREAST FEEDING SECTION

Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children.

PACKAGE LABEL

NEWTON homeopathics
Nurturing Naturally Since 1987™

NDC# 55714-2222-1

Menstrual ~PMS

Formulated for associated symptoms such as irregularity, cramping, bloating, headache, cravings, emotional upsets and mood swings.

1 fl oz (29.57 ml)

Directions: ORAL USE ONLY - SHAKE WELL.
Ages 12 and up, take 6 drops orally as needed or as directed by a healthcare professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

Active Ingredients: Angelica sinensis radix 15x, Arsenicum alb. 15x, Bryonia 15x, Caulophyllum 15x, Cimicifuga 15x, Cinchona 15x, Dioscorea 15x, Folliculinum 15x, Gelsemium 15x, Lachesis 15x, Lilium 15x, Lycopodium 15x, Millefolium 15x, Nux vom. 15x, Pulsatilla 15x, Sabina 15x, Secale 15x, Sepia 15x, Thlaspi 15x, Viburnum op. 15x, Zingiber 15x, Dioscorea 3x, Echinacea 3x, Valeriana 3x.

Inactive Ingredients: USP Purified water; USP Gluten-free, non-GMO, organic cane dispensing alcohol 20%.

Stock# N012 Lot#

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MENSTRUAL - PMS

angelica sinensis radix, arsenicum alb., bryonia, caulophyllum, cimicifuga, cinchona, dioscorea, folliculinum, gelsemium, lachesis, lilium, lycopodium, millefolium, nux vom., pulsatilla, sabina, secale, sepia, thlaspi, viburnum op., zingiber, echinacea, valeriana liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-2222
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Angelica Sinensis Root (UNII: B66F4574UG) (Angelica Sinensis Root - UNII:B66F4574UG)	Angelica Sinensis Root	15 [hp_X] in 1 mL
Arsenic Trioxide (UNII: S7V92P67HO) (Arsenic Cation (3+) - UNII:C96613F5AV)	Arsenic Trioxide	15 [hp_X] in 1 mL
Bryonia Alba Root (UNII: T7J046YI2B) (Bryonia Alba Root - UNII:T7J046YI2B)	Bryonia Alba Root	15 [hp_X] in 1 mL
Caulophyllum Thalictroides Root (UNII: JTJ6HH6YEH) (Caulophyllum Thalictroides Root - UNII:JTJ6HH6YEH)	Caulophyllum Thalictroides Root	15 [hp_X] in 1 mL
Black Cohosh (UNII: K73E24S6X9) (Black Cohosh - UNII:K73E24S6X9)	Black Cohosh	15 [hp_X] in 1 mL
Cinchona Officinalis Bark (UNII: S003A158SB) (Cinchona Officinalis Bark - UNII:S003A158SB)	Cinchona Officinalis Bark	15 [hp_X] in 1 mL

UNII:S003A158SB)	<i>Siphocampylus</i> <i>officinalis</i> <i>Bark</i>	in 1 mL
Dioscorea Villosa Tuber (UNII: IWY3IWX2G8) (Dioscorea Villosa Tuber - UNII:IWY3IWX2G8)	Dioscorea Villosa Tuber	15 [hp_X] in 1 mL
Estrone (UNII: 2DI9HA706A) (Estrone - UNII:2DI9HA706A)	Estrone	15 [hp_X] in 1 mL
Gelsemium Sempervirens Root (UNII: 639KR60Q1Q) (Gelsemium Sempervirens Root - UNII:639KR60Q1Q)	Gelsemium Sempervirens Root	15 [hp_X] in 1 mL
Lachesis Muta Venom (UNII: VSW71SS07I) (Lachesis Muta Venom - UNII:VSW71SS07I)	Lachesis Muta Venom	15 [hp_X] in 1 mL
Lilium Lancifolium Whole Flowering (UNII: X67Z2963PI) (Lilium Lancifolium Whole Flowering - UNII:X67Z2963PI)	Lilium Lancifolium Whole Flowering	15 [hp_X] in 1 mL
Lycopodium Clavatum Spore (UNII: C88X29Y479) (Lycopodium Clavatum Spore - UNII:C88X29Y479)	Lycopodium Clavatum Spore	15 [hp_X] in 1 mL
Achillea Millefolium (UNII: 2FXJ6SW4PK) (Achillea Millefolium - UNII:2FXJ6SW4PK)	Achillea Millefolium	15 [hp_X] in 1 mL
Strychnos Nux-vomica Seed (UNII: 269XH13919) (Strychnos Nux-vomica Seed - UNII:269XH13919)	Strychnos Nux-vomica Seed	15 [hp_X] in 1 mL
Pulsatilla Vulgaris (UNII: I76KB35JEV) (Pulsatilla Vulgaris - UNII:I76KB35JEV)	Pulsatilla Vulgaris	15 [hp_X] in 1 mL
Juniperus Sabina Leafy Twig (UNII: Z5BEX9K2G1) (Juniperus Sabina Leafy Twig - UNII:Z5BEX9K2G1)	Juniperus Sabina Leafy Twig	15 [hp_X] in 1 mL
Claviceps Purpurea Sclerotium (UNII: 01G9XEA93N) (Claviceps Purpurea Sclerotium - UNII:01G9XEA93N)	Claviceps Purpurea Sclerotium	15 [hp_X] in 1 mL
Sepia Officinalis Juice (UNII: QDL83WN8C2) (Sepia Officinalis Juice - UNII:QDL83WN8C2)	Sepia Officinalis Juice	15 [hp_X] in 1 mL
Capsella Bursa-pastoris (UNII: W0X9457M59) (Capsella Bursa-pastoris - UNII:W0X9457M59)	Capsella Bursa-pastoris	15 [hp_X] in 1 mL
Viburnum Opulus Bark (UNII: T1UG6H6805) (Viburnum Opulus Bark - UNII:T1UG6H6805)	Viburnum Opulus Bark	15 [hp_X] in 1 mL
Ginger (UNII: C5529G5JPQ) (Ginger - UNII:C5529G5JPQ)	Ginger	15 [hp_X] in 1 mL
Echinacea, Unspecified (UNII: 4N9P6CC1DX) (Echinacea, Unspecified - UNII:4N9P6CC1DX)	Echinacea, Unspecified	3 [hp_X] in 1 mL
Valerian (UNII: JWF5YAW3QW) (Valerian - UNII:JWF5YAW3QW)	Valerian	3 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Alcohol (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-2222-1	29.57 mL in 1 BOTTLE, GLASS		
2	NDC:55714-2222-2	59.14 mL in 1 BOTTLE, GLASS		
3	NDC:55714-2222-0	.5 mL in 1 BOTTLE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		03/01/2011	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	MANUFACTURE(55714-2222)

Revised: 3/2011

Newton Laboratories, Inc.