

ESTROGEN AND PROGESTERONE- agnus castus, angelica sinensis, apis mellifica, arnica montana, cimicifuga racemosa, estradiol, estriol, folliculinum, galium aparine, glycyrrhiza glabra, korean ginseng, oophorinum (suis), progesterone, sepia, thuja occidentalis, viscum album spray

ProBLEN

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:

Agnus Castus 3X, Angelica Sinensis 3X, Apis Mellifica 6X, Arnica Montana 6X, Cimicifuga Racemosa 3X, Estradiol 9C, Estriol 9C, Folliculinum 9C, Galium Aparine 3X, Glycyrrhiza Glabra 3X, Korean Ginseng 3X, Oophorinum (Suis) 30C, Progesterone 6X, Sepia 30C, Thuja Occidentalis 6X, Viscum Album 3X

INDICATIONS:

Temporarily supports the body to rebalance estrogen output. Symptoms may include: mood swings, hot flashes, irritability, lack of energy.

WARNINGS:

Not for use on children.

If symptoms continue to recur, or if sleeplessness persists continuously for more than two weeks, consult a physician. Insomnia may be a symptom of a serious underlying medical illness.

As with all medicines, **if you are pregnant or breast feeding**, consult a health professional before using this product.

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Tamper Evident. There is a seal around the neck of the bottle. Do not use if this seal is broken or missing.

KEEP OUT OF REACH OF CHILDREN:

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

Adults: Hold the spray-top close to your open mouth and spray twice directly under your tongue, three times a day. Some people notice improvement within two or three weeks, others take longer.

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INACTIVE INGREDIENTS:

Organic Alcohol 30% v/v, Purified Water

QUESTIONS:

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2850 Shoreline Trail,
Rockwall, TX 75032
www.problen.com

PACKAGE LABEL DISPLAY:

HOMEOPATHIC

ORGANOTHERAPY

Estro

gen

&

Progesterone

1.0 FL. OZ. (30ML)

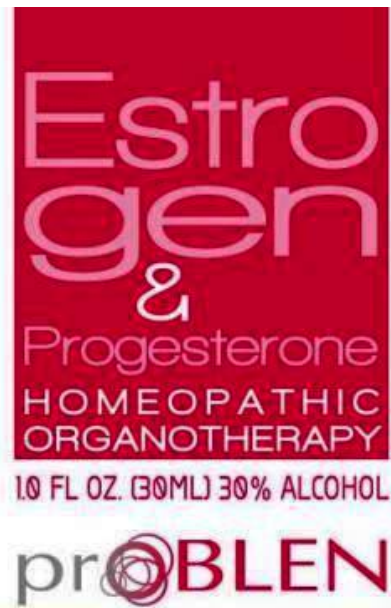
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Inactive Ingredients: Organic Alcohol 30% v/v, Purified Water

PROBLEM

HOMEOPATHIC
ORGANOTHERAPY

Estrogen
&
Progesterone

1.0 FL OZ. (30ML) 30% ALCOHOL



proBLEM

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ESTROGEN AND PROGESTERONE

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43853-0017
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHASTE TREE (UNII: 4330SF3U8A) (CHASTE TREE - UNII:4330SF3U8A)	CHASTE TREE	3 [hp_X] in 1 mL
ANGELICA SINENSIS ROOT (UNII: B66F4574UG) (ANGELICA SINENSIS ROOT - UNII:B66F4574UG)	ANGELICA SINENSIS ROOT	3 [hp_X] in 1 mL
APIS MELLIFERA (UNII: 7S82P3R43Z) (APIS MELLIFERA - UNII:7S82P3R43Z)	APIS MELLIFERA	6 [hp_X] in 1 mL
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	6 [hp_X] in 1 mL
BLACK COHOSH (UNII: K73E24S6X9) (BLACK COHOSH - UNII:K73E24S6X9)	BLACK COHOSH	3 [hp_X] in 1 mL

ESTRADIOL (UNII: 4T198Z838E) (ESTRADIOL - UNII:4T198Z838E)	ESTRADIOL	9 [hp_C] in 1 mL
ESTRIOL (UNII: FB33469R8E) (ESTRIOL - UNII:FB33469R8E)	ESTRIOL	9 [hp_C] in 1 mL
ESTRONE (UNII: 2D19HA706A) (ESTRONE - UNII:2D19HA706A)	ESTRONE	9 [hp_C] in 1 mL
GALIUM APARINE (UNII: Z4B6561488) (GALIUM APARINE - UNII:Z4B6561488)	GALIUM APARINE	3 [hp_X] in 1 mL
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H) (GLYCYRRHIZA GLABRA - UNII:2788Z9758H)	GLYCYRRHIZA GLABRA	3 [hp_X] in 1 mL
ASIAN GINSENG (UNII: CUQ3A77YXI) (ASIAN GINSENG - UNII:CUQ3A77YXI)	ASIAN GINSENG	3 [hp_X] in 1 mL
SUS SCROFA OVARY (UNII: S7YTV04R8O) (SUS SCROFA OVARY - UNII:S7YTV04R8O)	SUS SCROFA OVARY	30 [hp_C] in 1 mL
PROGESTERONE (UNII: 4G7DS2Q64Y) (PROGESTERONE - UNII:4G7DS2Q64Y)	PROGESTERONE	6 [hp_X] in 1 mL
SEPIA OFFICINALIS JUICE (UNII: QDL83WN8C2) (SEPIA OFFICINALIS JUICE - UNII:QDL83WN8C2)	SEPIA OFFICINALIS JUICE	30 [hp_C] in 1 mL
THUJA OCCIDENTALIS LEAFY TWIG (UNII: 1NT28V9397) (THUJA OCCIDENTALIS LEAFY TWIG - UNII:1NT28V9397)	THUJA OCCIDENTALIS LEAFY TWIG	6 [hp_X] in 1 mL
VISCUM ALBUM FRUITING TOP (UNII: BK9092J5MP) (VISCUM ALBUM FRUITING TOP - UNII:BK9092J5MP)	VISCUM ALBUM FRUITING TOP	3 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43853-0017-2	1 in 1 CARTON	01/12/2017	
1	NDC:43853-0017-1	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		01/12/2017	

Labeler - ProBLEN (838787161)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(43853-0017) , api manufacture(43853-0017) , label(43853-0017) , pack(43853-0017)

