

SERENE SLEEP- eschscholtzia californica, chamomilla, cina, coffea cruda, nux vomica, passiflora incarnata, pulsatilla (pratensis), ignatia amara, kali phosphoricum, rhus tox spray
The Wellness Center for Research a

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:

Eschscholtzia Californica 3C, Chamomilla 3C, 6C, 30C, Cina 6C, 30C, Coffea Cruda 6C, 30C, Nux Vomica 6C, 30C, Passiflora Incarnata 6C, 30C, Pulsatilla (Pratensis) 6C, 30C, Ignatia Amara 30C, Kali Phosphoricum 30C, Rhus Tox 30C.

INDICATIONS:

Supports a reduction in stress-related sleep issues, nightmares, waking during the early morning hours. Temporary relief of nervousness, anxiety, restlessness. overactive mind, mood disorders, grief, muscular discomfort.

WARNINGS:

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

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

Do not use if seal is broken or missing.

KEEP OUT OF REACH OF CHILDREN SECTION

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

DIRECTIONS:

Spray orally, 4 to 6 sprays, at least 30 minutes before bed and 30 minutes after eating. Consult a physician for use in children under 12 years of age.

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INACTIVE INGREDIENTS:

Demineralized Water, 25% Organic Ethanol

QUESTIONS:

MFD FOR:

The Wellness Center for Research
and Education, Inc.

1237 S. Victoria Ave. Suite 169

Oxnard, CA 93035

PACKAGE DISPLAY LABEL:

Formulated by DR. Theresa Dale

NDC#: 50181-0080-1

Serene

Sleep

DR. DALE'S WELLNESS CENTER

Homeopathic

1 fluid oz. (30 ml)

Formulated by Dr. Theresa Dale

DIRECTIONS: Spray orally, 4 to 6 sprays, at least 30 minutes before bed and 30 minutes after eating. Consult a physician for use in children under 12 years of age.

ACTIVE INGREDIENTS:

Eschscholtzia 3C, Chamomilla 3C, 6C, 30C, Cina 6C, 30C, Coffea Cruda 6C, 30C, Nux Vom 6C, 30C, Passiflora 6C, 30C, Pulsatilla 6C, 30C, Ignatia 30C, Kali Phos 30C, Rhus Tox 30C.

INACTIVE INGREDIENTS:

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**Serene
Sleep**



HOMEOPATHIC

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1237 S. Victoria Ave., Suite 169
Oxnard, CA 93035

LOT: XXXXXX

SERENE SLEEP

eschscholtzia californica, chamomilla, cina, coffea cruda, nux vomica, passiflora incarnata, pulsatilla (pratensis), ignatia amara, kali phosphoricum, rhus tox spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50181-0080
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ESCHSCHOLZIA CALIFORNICA WHOLE (UNII: 9315HN272X) (ESCHSCHOLZIA CALIFORNICA - UNII:9315HN272X)	ESCHSCHOLZIA CALIFORNICA WHOLE	3 [hp_C] in 1 mL
MATRICARIA CHAMOMILLA WHOLE (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA WHOLE	3 [hp_C] in 1 mL
ARTEMISIA CINA PRE-FLOWERING TOP (UNII: 28M1820ACT) (ARTEMISIA CINA FLOWER - UNII:28M1820ACT)	ARTEMISIA CINA PRE-FLOWERING TOP	6 [hp_C] in 1 mL
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	6 [hp_C] in 1 mL
STRYCHNOS NUX-VOMICA SEED (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	6 [hp_C] in 1 mL
PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS110) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS110)	PASSIFLORA INCARNATA FLOWERING TOP	6 [hp_C] in 1 mL
PULSATILLA PRATENSIS WHOLE (UNII: 8E272251DI) (PULSATILLA PRATENSIS WHOLE - UNII:8E272251DI)	PULSATILLA PRATENSIS WHOLE	6 [hp_C] in 1 mL
STRYCHNOS IGNATII SEED (UNII: 1NM3M2487K) (STRYCHNOS IGNATII SEED - UNII:1NM3M2487K)	STRYCHNOS IGNATII SEED	30 [hp_C] in 1 mL
DIBASIC POTASSIUM PHOSPHATE (UNII: CI71S98N1Z) (PHOSPHATE ION - UNII:NK08V8K8HR)	DIBASIC POTASSIUM PHOSPHATE	30 [hp_C] in 1 mL
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	30 [hp_C] 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:50181-0080-1	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	02/14/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		02/14/2022	

Registrant - Apotheca Company (844330915)**Establishment**

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(50181-0080) , api manufacture(50181-0080) , label(50181-0080) , pack(50181-0080)

Revised: 2/2022

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