

QUIET CALM- avena sativa, ammonium bromatum, chamomilla, coffea cruda, gelsemium sempervirens, l-tryptophan, phosphoricum acidum, valeriana officinalis liquid
Holistic Haven

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:

Avena Sativa 1X, Ammonium Bromatum 3X, Chamomilla 6X, Coffea Cruda 6X, Gelsemium Sempervirens 6X, L-Tryptophan 6X, Phosphoricum Acidum 6X, Valeriana Officinalis 30X.

INDICATIONS:

For the temporary relief of symptoms related to sleep dysfunction, mood swings, and nervous anxiety.

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 physician or Poison Control Center right away.

Do not use if seal is broken or missing.

Store in a cool dry place.

KEEP OUT OF REACH OF CHILDREN:

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

DIRECTIONS:

10 drops orally, 3 times a day or as directed by a health care professional. Consult a physician for use in children under 12 years of age.

INDICATIONS:

For the temporary relief of symptoms related to sleep dysfunction, mood swings, and nervous anxiety.

INACTIVE INGREDIENTS:

Demineralized Water, 25% Ethanol

QUESTIONS:

Dist. By: Holistic Haven

Westlake Village, CA 91362

holistichavenpharmacy.com

1-866-676-HEAL

PACKAGE LABEL DISPLAY:

Holistic Haven

Quiet

Calm

HOMEOPATHIC

2 FL OZ (59 ml)

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 tamper evident seal is broken or missing. Store in a cool, dry place.

INDICATIONS: For the temporary relief of symptoms related to sleep dysfunction, mood swings and nervous anxiety.

Lot:

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70476-0004
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVENA SATIVA FLOWERING TOP (UNII: MA9CQJ3F7F) (AVENA SATIVA FLOWERING TOP - UNII:MA9CQJ3F7F)	AVENA SATIVA FLOWERING TOP	1 [hp_X] in 1 mL
AMMONIUM BROMIDE (UNII: R0JB3224WS) (BROMIDE ION - UNII:952902IX06)	AMMONIUM BROMIDE	3 [hp_X] in 1 mL
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	6 [hp_X] in 1 mL
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	6 [hp_X] in 1 mL
GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	6 [hp_X] in 1 mL
TRYPTOPHAN (UNII: 8DUH1N11BX) (TRYPTOPHAN - UNII:8DUH1N11BX)	TRYPTOPHAN	6 [hp_X] in 1 mL
PHOSPHORIC ACID (UNII: E4GA8884NN) (PHOSPHORIC ACID - UNII:E4GA8884NN)	PHOSPHORIC ACID	6 [hp_X] in 1 mL
VALERIAN (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	30 [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:70476-0004-1	59 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	10/10/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/10/2019	

Labeler - Holistic Haven (005153286)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(70476-0004) , api manufacture(70476-0004) , label(70476-0004) , pack(70476-0004)

