

AHH SLEEP- coffea cruda spray

Micro Balance Health Products

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.

Indication

Temporarily relieves symptoms associated with sleeplessness such as the inability to fall asleep or return to sleep after waking, restlessness, nervousness, worry, and excitability, to restore a more natural sleep pattern.

Directions

Adults and children over 12: Apply 2-4 sprays under the tongue before bedtime. For best results, hold spray under the tongue 15 seconds before swallow. Additional sprays may be taken during the night as needed. Do not take within 15 minutes of consuming food or brushing teeth.

Active ingredients

Coffea cruda (coffee) 200 C□
Cypripedium (Lady's Slipper Orchid) 4x,
Hyoscyamus Niger (Henbane) 30C;
Ignatia Amara 12X;
Kalium Phosphoricum (Potassium Phosphate) 12X,
Muriaticum Acidum (Muriatic Acid) 12X;
Sulphur 6X;
Zincum Metallicum (Zinc) 12X

Inactive Ingredients

Alcohol USP 20%;
Water

Warnings

If you are pregnant, breastfeeding, or for use in children under 12, consult with a healthcare professional. In case of accidental overdose, get medical help or contact a Poison Control Center right away. If symptoms worsen or persist for more than 2 weeks, consult a physician.

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83018-0004
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS ROOT (UNII: 21Y9GZ1LZA) (CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS ROOT - UNII:21Y9GZ1LZA)	CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS ROOT	4 [hp_X] in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB) (HYDROCHLORIC ACID - UNII:QTT17582CB)	HYDROCHLORIC ACID	12 [hp_X] in 1 mL
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	200 [hp_C] in 1 mL
STRYCHNOS IGNATII SEED (UNII: 1NM3M2487K) (STRYCHNOS IGNATII SEED - UNII:1NM3M2487K)	STRYCHNOS IGNATII SEED	12 [hp_X] in 1 mL
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	12 [hp_X] in 1 mL
HYOSCYAMUS NIGER (UNII: 4WRK2153H3) (HYOSCYAMUS NIGER - UNII:4WRK2153H3)	HYOSCYAMUS NIGER	30 [hp_C] in 1 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	6 [hp_X] in 1 mL
POTASSIUM PHOSPHATE, UNSPECIFIED FORM (UNII: B7862WZ632) (POTASSIUM PHOSPHATE, UNSPECIFIED FORM - UNII:B7862WZ632)	POTASSIUM PHOSPHATE, UNSPECIFIED FORM	12 [hp_X] in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83018-0004-1	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/30/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/30/2023	

Labeler - Micro Balance Health Products (025495088)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratoire Schmidt-Nagel		203869883	manufacture(83018-0004)

Revised: 10/2023

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