

SLEEP AID- aconitum nap, aesculus hipp, flos, arsenicum alb, avena, belladonna, camphora, cinchona, coffea cruda, cypripedium, hyoscyamus, ignatia, passiflora, pulsatilla, valeriana. liquid King Bio 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.

Sleep Aid™

Drug Facts

HPUS active ingredients: Aconitum nap, Aesculus hipp, flos, Arsenicum alb, Avena, Belladonna, Camphora, Cinchona, Coffea cruda, Cypripedium, Hyoscyamus, Ignatia, Passiflora, Pulsatilla, Valerian.

Equal volumes of each ingredient in 10X, 30X, 100X, 1LM, 2LM, 3LM, 5LM potencies.

Uses for relief of symptoms due to occasional sleeplessness: inability to fall or stay asleep, restless tossing, fear and worry, light sleeping, and overactive mind.

Inactive Ingredients: Bio-Energetically Enhanced™ pure water, Carya ova bark extract, citrus extract, Lonicera japonica (honeysuckle), polylysine, steviol glycosides.

Warnings

- **Stop use and ask your doctor** if symptoms persist or worsen.
- **If pregnant or breast-feeding**, take only on advice of a healthcare professional.
- **Keep out of reach of children.**

Directions

- Initially, depress pump until primed.
- Spray one dose directly into mouth.
- **Adults 12 and up: 3 sprays 3 times per day.**
- **Children 2-12: 2 sprays 3 times per day.**
- **Children 2 mo.-2yr: 1 spray 3 times per day.**

Tamper resistant for your protection. Use only if safety seal is intact. This product has not been clinically tested.

Uses for relief of symptoms due to occasional sleeplessness:

- inability to fall or stay asleep
- restless tossing
- fear and worry
- light sleeping
- overactive mind

The image shows the front and side of a Sleep Aid product box. The front panel features the 'Dr. King's SafeCareRx' logo at the top, followed by 'Sleep Aid' in large bold letters. Below that, it says 'Sleep' and 'High Potency Homeopathic Formula for Professional Use Only' in a green banner, and '2 fl oz (59 mL)' at the bottom. The side panel has a barcode with the number '3 57955 26392 0' and 'Exp. 02/20 Lot # 022318F'. The back panel has a 'Drug Facts' section with the following text: 'HPUS active ingredients: Aconitum nap, Aesculus hipp flos, Arsenicum alb, Avena, Belladonna, Camphora, Cinchona, Coffea cruda, Cypripedium, Hyoscyamus, Ignatia, Passiflora, Pulsatilla, Valeriana. Equal volumes of each ingredient in 10X, 30X, 100X, 1LM, 2LM, 3LM, 5LM potencies. Uses for relief of symptoms due to occasional sleeplessness: inability to fall or stay asleep, restless tossing, fear and worry, light sleeping, and overactive mind. Inactive ingredients: Bio-Energetically Enhanced™ pure water, Carya ovata bark extract, citrus extract, Lonicera japonica (honeysuckle), polylysine, steviol glycosides.'

SLEEP AID

aconitum nap, aesculus hipp, flos, arsenicum alb, avena, belladonna, camphora, cinchona, coffea cruda,

cypridium, hyoscyamus, ignatia, passiflora, pulsatilla, valeriana. liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57955-2641
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	59 [hp_X] in 59 mL
AESCLUS HIPPOCASTANUM FLOWER (UNII: KK0Z92II8M) (AESCLUS HIPPOCASTANUM FLOWER - UNII:KK0Z92II8M)	AESCLUS HIPPOCASTANUM FLOWER	59 [hp_X] in 59 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	59 [hp_X] in 59 mL
AVENA SATIVA FLOWERING TOP (UNII: MA9CQJ3F7F) (AVENA SATIVA FLOWERING TOP - UNII:MA9CQJ3F7F)	AVENA SATIVA FLOWERING TOP	59 [hp_X] in 59 mL
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	59 [hp_X] in 59 mL
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	59 [hp_X] in 59 mL
CINCHONA OFFICINALIS BARK (UNII: S003A158SB) (CINCHONA OFFICINALIS BARK - UNII:S003A158SB)	CINCHONA OFFICINALIS BARK	59 [hp_X] in 59 mL
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	59 [hp_X] in 59 mL
CYPRIPEDIUM PARVIFOLUM ROOT (UNII: 21Y9GZ1LZA) (CYPRIPEDIUM PARVIFOLUM ROOT - UNII:21Y9GZ1LZA)	CYPRIPEDIUM PARVIFOLUM ROOT	59 [hp_X] in 59 mL
HYOSCYAMUS NIGER (UNII: 4WRK2153H3) (HYOSCYAMUS NIGER - UNII:4WRK2153H3)	HYOSCYAMUS NIGER	59 [hp_X] in 59 mL
STRYCHNOS IGNATII SEED (UNII: 1NM3M2487K) (STRYCHNOS IGNATII SEED - UNII:1NM3M2487K)	STRYCHNOS IGNATII SEED	59 [hp_X] in 59 mL
PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS11O) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS11O)	PASSIFLORA INCARNATA FLOWERING TOP	59 [hp_X] in 59 mL
PULSATILLA VULGARIS (UNII: I76KB35JEV) (PULSATILLA VULGARIS - UNII:I76KB35JEV)	PULSATILLA VULGARIS	59 [hp_X] in 59 mL
VALERIAN (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	59 [hp_X] in 59 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CARYA OVATA BARK (UNII: X765CF609L)	
CITRUS BIOFLAVONOIDS (UNII: BD70459I50)	
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)	
POLYEPSILON-LYSINE (4000 MW) (UNII: WB0M8X4TWR)	
REBAUDIOSIDE A (UNII: B3FUD0528F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57955-2641-2	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/24/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		04/24/2018	

Labeler - King Bio Inc. (617901350)

Registrant - King Bio Inc. (617901350)

Establishment

Name	Address	ID/FEI	Business Operations
King Bio Inc.		617901350	manufacture(57955-2641)

Revised: 4/2018

King Bio Inc.