

SLEEP WELL T012- arsenicum album, avena sativa, coffea cruda, kali carbonicum, magnesia carbonica, nux vomica, passiflora incarnata, sepia, valeriana officinalis liquid
Guangzhou Renuma Medical Systems Co., Ltd

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:

Arsenicum Album 30X, Avena Sativa 30X, Coffea Cruda 30X, Kali Carbonicum 30X, Magnesia Carbonica 30X, Nux Vomica 30X, Passiflora Incarnata 30X, Sepia 30X, Valeriana Officinalis 30X.

INDICATIONS:

May temporarily relieve symptoms due to fatigue and restlessness from inability to sleep.

WARNINGS:

If pregnant or breast-feeding, ask a health care 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 cool, dry place.

KEEP OUT OF REACH OF CHILDREN:

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

DIRECTIONS:

Adults and children 5 to 10 drops orally, 3 times daily or as otherwise directed by a health care professional. If symptoms persist, consult your health care professional. Consult a physician for use in children under 12 years of age.

INDICATIONS:

May temporarily relieve symptoms due to fatigue and restlessness from inability to sleep.

INACTIVE INGREDIENTS:

Demineralized water, Glycerin

QUESTIONS:

Distributed by:

Guangzhou Renuma Medical
Systems Co., Ltd.

No. 5, 2nd Floor, Ascendas 2nd Street

Sino-Singapore Guangzhou Knowledge City
Guangzhou 510555, China

PACKAGE LABEL DISPLAY:

SLEEP WELL
T012
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.

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LOT XXXXXX

SLEEP WELL
T012

HOMEOPATHIC

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SLEEP WELL T012

arsenicum album, avena sativa, coffea cruda, kali carbonicum, magnesia carbonica, nux vomica, passiflora incarnata, sepia, valeriana officinalis liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71742-0006
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	30 [hp_X] in 1 mL
AVENA SATIVA FLOWERING TOP (UNII: MA9CQJ3F7F) (AVENA SATIVA FLOWERING TOP - UNII:MA9CQJ3F7F)	AVENA SATIVA FLOWERING TOP	30 [hp_X] in 1 mL
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	30 [hp_X] in 1 mL
POTASSIUM CARBONATE (UNII: BQN1B9B9HA) (CARBONATE ION - UNII:7UJQ5OPE7D)	POTASSIUM CARBONATE	30 [hp_X] in 1 mL
MAGNESIUM CARBONATE (UNII: 0E53J927NA) (CARBONATE ION - UNII:7UJQ5OPE7D)	MAGNESIUM CARBONATE	30 [hp_X] in 1 mL
STRYCHNOS NUX-VOMICA SEED (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	30 [hp_X] in 1 mL

PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS11O) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS11O)	PASSIFLORA INCARNATA FLOWERING TOP	30 [hp_X] in 1 mL
SEPIA OFFICINALIS JUICE (UNII: QDL83WN8C2) (SEPIA OFFICINALIS JUICE - UNII:QDL83WN8C2)	SEPIA OFFICINALIS JUICE	30 [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)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71742-0006-1	59 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	10/24/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/24/2017	

Labeler - Guangzhou Renuma Medical Systems Co., Ltd (544538706)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(71742-0006) , api manufacture(71742-0006) , label(71742-0006) , pack(71742-0006)

Revised: 10/2017

Guangzhou Renuma Medical Systems Co., Ltd