RXHOMEO HOMEOPATHIC COMBO- rxhomeo homeopathic combo Rxhomeo Private Limited d.b.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.

ACTIVE INGREDIENT

PASSIFLORA INCARNATA HPUS 3X and higher KALI PHOSPHORICUM HPUS 1X and Higher

USES

A homeopathic combination pack with two single remedies Passiflora Incarnata and Kali Phosphoricum for relief of sleeplessness.

Passiflora Incarnata; Uses: Passiflora Incarnata is a chief remedy for insomnia or sleeplessness. Passiflora helps in quietning the nervous system and induces normal sleep. Restlessness and wakeful sleep especially in the feeble, infants, and the aged with history of mental worries and over work.

Kali Phosphoricum;Uses: Kali Phosphoricum helps in insomnia or sleeplessness after worry or excitement from nervous causes. Also walking in sleep in children.

INDICATIONS

Condition listed above or as directed by the physician

DOSAGE

PELLETS included in the Combo

Adults- Take 4 or 6 Pellets by mouth, three times daily or as suggested by physician. Children 2 years and older- take 1/2 the adult dose.

TABLETS included in the Combo

Adults- Take 4 or 6 Tablets by mouth, three times daily or as suggested by physician. Children 2 years and older- take 1/2 the adult dose.

WARNINGS

This product is to be used for self-limiting conditions

If symptoms do not improve in 4 days, or worsen, discontinue use and seek assistance of health professional

Keep this and all medication out of reach of children

Do not use if capseal is broken or missing.

Close the cap tightly after use.

INACTIVE INGREDIENTS

Sucrose for Pellets.

Lactose for Tablets.

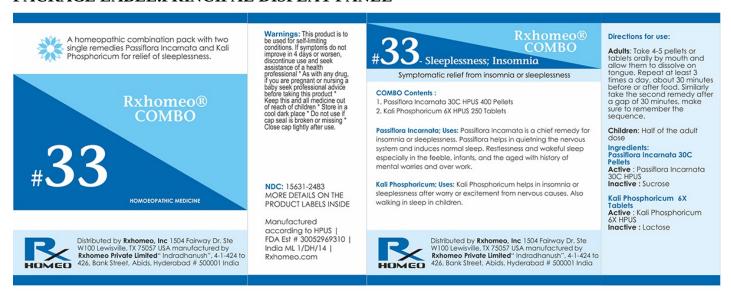
STORAGE

Store in a cool dark place

QUESTIONS OR COMMENTS

www.Rxhomeo.com | 1.888.2796642 | info@rxhomeo.com Rxhomeo, Inc 1504 Fairway Dr. Ste W 100 Lewisville, TX 75057 USA

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



RXHOMEO HOMEOPATHIC COMBO

rxhomeo homeopathic combo kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:15631-2483

Packaging

7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:15631-2483-0	1 in 1 CONTAINER	10/10/2016	

Ouantity of Parts

Part #	Package Quantity	Total Product Quantity	
Part 1		1	
Part 2		1	

Part 1 of 2

PASSIFLORA INCARNATA

passiflora incarnata pellet

Product Information

Item Code (Source) NDC:15631-0331

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength
PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS110) (PASSIFLORA
PASSIFLORA INCARNATA

INCARNATA FLOWERING TOP - UNII:CLF5YFS110)

FLOWERING TOP

1 [hp_X]

Inactive Ingredients

Ingredient Name Strength

SUCROSE (UNII: C151H8M554)

Marketing Information

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

Part 2 of 2

KALI PHOSPHORICUM

kali phosphoricum tablet

Product Information

Item Code (Source) NDC:15631-0612

Route of Administration ORAL

Active Ingredient/Active Moiety

0	J		
In	gredient Name	Basis of Strength	Strength
POTASSIUM PHOSPHATE, DIBAS UNII:NK08V8K8HR)	C (UNII: CI71S98N1Z) (PHOSPHATE ION -	POTASSIUM PHOSPHATE, DIBASIC	1 [hp_X]

Inactive 1	ing re d	die nts
IIIacire .		are mes

Ingredient Name	Strength
LACTOSE (UNII: J2B2A4N98G)	

Product Characteristics						
Color	white	Score	no score			
Shape	ROUND	Size	3mm			
Flavor		Imprint Code				
Contains						

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved homeopathic				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved homeopathic		10/10/2016		

Labeler - Rxhomeo Private Limited d.b.a. (650833994)

Establishment				
Name	Address	ID/FEI	Business Operations	
Rxhomeo Private Limited d.b.a. Rxhomeo, Inc		650833994	manufacture(15631-2483), label(15631-2483)	

Revised: 10/2016 Rxhomeo Private Limited d.b.a.