

**PASSIFLORA INCARNATA- passiflora incarnata tablet**  
**Rxhomeo Private Limited d.b.a. Rxhomeo, 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.*

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**ACTIVE INGREDIENT**

PASSIFLORA INCARNATA HPUS 1X and Higher

**USES**

Insomnia

**INDICATIONS**

Condition listed above or as directed by the physician

**DOSAGE**

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

As with any drug, if you are pregnant, or nursing a baby, seek professional advice before taking this product

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**

Lactose

**STORAGE**

Store in a cool dark place

**QUESTIONS OR COMMENTS**

[www.Rxhomeo.com](http://www.Rxhomeo.com) | 1.888.2796642 | [info@rxhomeo.com](mailto:info@rxhomeo.com)

Rxhomeo, Inc 9415 Burnet Road, Suite 312, Austin, TX 78758

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**



# PASSIFLORA INCARNATA 1X

**Ingredients:** Active: As Above, Inactive: Lactose  
USES: Insomnia



**Dosage:** Adults - Take 4 or 6 tablets by mouth, three times daily or as directed 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 a health professional \* As with any drug, if you are pregnant or nursing a baby, seek professional advice before taking this product! \* Keep this and all medication out of reach of children \* Store in a cool dark place \* Do not use if capseal is broken or missing \* Close cap tightly after use.



Distributed in the US by Rxhomeo, Inc 9415 Burnet Road, Suite 312, Austin, TX 78758 Manufactured by: Rxhomeo Private Limited "Indradhanush", 4-1-424 to 426, Bank Street, Abids, Hyderabad #500001 India.

NDC 15631-0648-3 B.No XXXXXXXXXX MFD XX/XX EXP XX/XX Contents 100 Tablets

Manufactured according to the Homeopathic Pharmacopoeia of the United States  
Est. # 30052969310  
info@rxhomeo.com Rxhomeo.com  
1-888-8RYONIA ( 2796642 )



## PASSIFLORA INCARNATA

passiflora incarnata tablet

### Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:15631-0648 |
| <b>Route of Administration</b> | ORAL           |                           |                |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength                  | Strength |
|--|------------------------------------|----------|
| PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS11O) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS11O) | PASSIFLORA INCARNATA FLOWERING TOP | 1 [hp_X] |

### Inactive Ingredients

| Ingredient Name            | Strength |
|----------------------------|----------|
| LACTOSE (UNII: J2B2A4N98G) |          |

### Product Characteristics

|                 |       |                     |          |
|-----------------|-------|---------------------|----------|
| <b>Color</b>    | white | <b>Score</b>        | no score |
| <b>Shape</b>    | ROUND | <b>Size</b>         | 3mm      |
| <b>Flavor</b>   |       | <b>Imprint Code</b> |          |
| <b>Contains</b> |       |                     |          |

### Packaging

| # | Item Code        | Package Description                                    | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:15631-0648-0 | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:15631-0648-1 | 4 in 1 BLISTER PACK; Type 0: Not a Combination Product |                      |                    |
| 3 | NDC:15631-0648-2 | 50 in 1 CONTAINER; Type 0: Not a Combination Product   |                      |                    |

|   |                  |   |  |  |
|---|------------------|---|--|--|
| 4 | NDC:15631-0648-3 | 100 in 1 CONTAINER; Type 0: Not a Combination Product   |  |  |
| 5 | NDC:15631-0648-4 | 250 in 1 CONTAINER; Type 0: Not a Combination Product   |  |  |
| 6 | NDC:15631-0648-5 | 500 in 1 CONTAINER; Type 0: Not a Combination Product   |  |  |
| 7 | NDC:15631-0648-6 | 1000 in 1 CONTAINER; Type 0: Not a Combination Product  |  |  |
| 8 | NDC:15631-0648-7 | 10000 in 1 CONTAINER; Type 0: Not a Combination Product |  |  |

## Marketing Information

| Marketing Category     | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| unapproved homeopathic |  | 12/26/2015           |                    |

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

## Establishment

| Name         | Address | ID/FEI    | Business Operations                    |
|--------------|---------|-----------|--|
| Rxhomeo, Inc |         | 832534981 | wholesale drug distributor(15631-0648) |

## Establishment

| Name  | Address | ID/FEI    | Business Operations                         |
|---|---------|-----------|---|
| Rxhomeo Private Limited d.b.a. Rxhomeo, Inc |         | 650833994 | manufacture(15631-0648) , label(15631-0648) |

Revised: 12/2015

Rxhomeo Private Limited d.b.a. Rxhomeo, Inc