# INSOMNIA DROPS 2035- insomnia drops liquid Professional Complementary Health Formulas

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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**C35** 

#### **ACTIVE INGREDIENTS**

Chamomilla 1X
Valeriana officinalis 1X
Avena sativa 2X
Zincum metallicum 3X
Passiflora incarnata 6X
Coffea cruda 6X, 12X, 30X
Paullinia sorbilis 24X

#### **QUESTIONS**

Professional Formulas
PO Box 2034 Lake Oswego, OR 97035

#### INDICATIONS

For the temporary relief of difficulty falling or staying asleep.\*

\*Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

#### **WARNINGS**

In case of overdose, get medical help or contact a poison control center right away. Keep out of the reach of children.

If pregnant or breastfeeding, ask a healthcare professional before use.

#### **DIRECTIONS**

Place drops under tongue 30 minutes before/after meals. Adults and children 12 years and over: Take 10 drops up to 3 times per day for up to 6 weeks. For immediate onset of symptoms, take 10 to 15 drops every 15 minutes up to 3 hours. For less severe symptoms, take 10-15 drops hourly up to 8 hours. Consult a physician for use in children under 12 years of age.

#### OTHER INFORMATION

Tamper resistant. If seal is broken, do not use. After opening, close container tightly and store at room temperature away from heat.

#### **INACTIVE INGREDIENTS**

20% ethanol, purified water.

#### **LABEL**

Est 1985

**Professional Formulas** 

Complementary Health

Insomnia Drops

Homeopathic Remedy

2 FL. OZ. (59 mL)



### **INSOMNIA DROPS 2035**

insomnia drops liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63083-2035	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
ARTEMISIA ANNUA FLOWERING TOP (UNII: 0UQK60820W) (ARTEMISIA ANNUA	ARTEMISIA ANNUA	1 [hp_X]		

FLOWERING TOP - UNII:0UQK6O82OW)	FLOWERING TOP	in 59 mL
VALERIAN (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	1 [hp_X] in 59 mL
AVENA SATIVA FLOWERING TOP (UNII: MA9CQJ3F7F) (AVENA SATIVA FLOWERING TOP - UNII:MA9CQJ3F7F)	AVENA SATIVA FLOWERING TOP	2 [hp_X] in 59 mL
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	3 [hp_X] in 59 mL
PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS110) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS110)	PASSIFLORA INCARNATA FLOWERING TOP	6 [hp_X] in 59 mL
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	6 [hp_X] in 59 mL
PAULLINIA CUPANA SEED (UNII: C21GE7524R) (PAULLINIA CUPANA SEED - UNII:C21GE7524R)	PAULLINIA CUPANA SEED	24 [hp_X] in 59 mL

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

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:63083- 2035-2	59 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	08/15/1985	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		08/15/1984	

## **Labeler -** Professional Complementary Health Formulas (167339027)

## **Registrant - Natural Pharmaceutical Manufacturing LLC (015624923)**

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Natural Pharmaceutical Manufacturing LLC		015624923	manufacture(63083-2035)	

Revised: 8/2019 Professional Complementary Health Formulas