

COMBINATION REMEDY 20 - INSOMNIA- coffea cruda, hyoscyamus niger, ignatia amara, passiflora incarnata, valeriana officinalis solution/ drops

Warsan Homoeopathic Laboratories

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.

Stop use and ask doctor if symptoms worsen or persist longer than 7 days.

If pregnant or breast-feeding, ask health professional before use.

Do not use if tamper evident seal is missing or broken.

Keep out of reach of children.

Coffea Cruda 1X

Hyoscyamus Niger 1X

Ignatia Amara 1X

Passiflora Incarnata 1X

Valeriana Officinalis 1x

Temporary relief from difficulty sleeping, unrefreshing sleep, daytime drowsiness, nervous exhaustion.

Purified Water

Alcohol

Adults and children 12 years and older: Take 10-15 drops in half cup of water 3 times a day.

Children 2 years to under 12 years: Take 8-10 drops in half cup of water of 3 times a day.

Children under 2 years: Consult doctor prior to use.

Temporary relief from difficulty sleeping, unrefreshing sleep, daytime drowsiness, nervous exhaustion.

NDC: 69008-4070-1 Homeopathic	<div style="border: 1px solid black; padding: 5px;"> <p>Drug Facts:</p> <p><i>Active Ingredient(s) HPUS... Purpose</i> Coffea Cruda 1X..... Sleeplessness Hyoscyamus Niger 1X..... Sleeplessness Ignatia Amara 1X.....Insomnia Passiflora Incarnata 1X..... Unrefreshing Sleep Valeriana Officinalis 1X..... Sleeplessness</p> <p>Use(s): Temporary relief from difficulty sleeping, unrefreshing sleep, daytime drowsiness, nervous exhaustion.</p> <p>Warnings: Stop use and ask doctor if symptoms worsen or persist longer than 7 days.</p> <p>Keep this and all medicine out of reach of children.</p> <p>If pregnant or breast-feeding, ask health professional before use.</p> <p>Do not use if cap seal is missing or broken. ▶</p> </div>	NDC: 69008-4070-1 Homeopathic	<div style="border: 1px solid black; padding: 5px;"> <p>Drug Facts (cont.):</p> <p>Directions:</p> <table border="1"> <thead> <tr> <th>Age</th> <th>Dose</th> </tr> </thead> <tbody> <tr> <td>Adults and children 12 years and over</td> <td>Take 12-15 drops in half cup of water 3 times a day.</td> </tr> <tr> <td>Children 2 years to under 12 years</td> <td>Take 8-10 drops in half cup of water 3 times a day.</td> </tr> <tr> <td>Children under 2 years</td> <td>Consult doctor prior to use</td> </tr> </tbody> </table> <p>Inactive Ingredient(s): Purified Water, Alcohol</p> <p>Other Information: Before use, replace bottle stopper with dropper.</p> <p>Seal cap tightly after use.</p> <p>Questions?: Call 1-703-626-4964</p> <p>Manufactured by Warsan Homeopathic by Warsan Homeopathic Laboratories Made in Pakistan</p> <p>Distributed by Warsan Homeopathic South Riding, VA, 20152 www.warsan.us</p> </div>	Age	Dose	Adults and children 12 years and over	Take 12-15 drops in half cup of water 3 times a day.	Children 2 years to under 12 years	Take 8-10 drops in half cup of water 3 times a day.	Children under 2 years	Consult doctor prior to use
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20 ml 61% Alcohol	20 ml 61% Alcohol										

COMBINATION REMEDY 20 - INSOMNIA

coffea cruda, hyoscyamus niger, ignatia amara, passiflora incarnata, valeriana officinalis solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69008-4070
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
STRYCHNOS IGNATII SEED (UNII: 1NM3M2487K) (STRYCHNOS IGNATII SEED - UNII:1NM3M2487K)	STRYCHNOS IGNATII SEED	1 [hp_X] in 1 mL
PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS11O) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS11O)	PASSIFLORA INCARNATA FLOWERING TOP	1 [hp_X] in 1 mL
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	1 [hp_X] in 1 mL
HYOSCYAMUS NIGER (UNII: 4WRK2153H3) (HYOSCYAMUS NIGER - UNII:4WRK2153H3)	HYOSCYAMUS NIGER	1 [hp_X] in 1 mL
VALERIAN (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	1 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69008-4070-1	20 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	11/16/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		11/15/2017	

Labeler - Warsan Homoeopathic Laboratories (645579772)

Registrant - Warsan Homoeopathic Laboratories (645579772)

Establishment

Name	Address	ID/FEI	Business Operations
Warsan Homoeopathic Laboratories		645579772	manufacture(69008-4070) , pack(69008-4070) , label(69008-4070)

Revised: 12/2017

Warsan Homoeopathic Laboratories