

SLEEP- hyoscyamus niger, strychnos ignatii seed, and potassium phosphate, dibasic tablet

Hyland's 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.

Hyland's Sleep

Relieves Occasional Sleeplessness Due to Nervousness or Worry

Drug Facts

Active ingredients	Purpose
Hyoscyamus Niger 6X HPUS (0.0000001% Alkaloids, calculated)	occasional sleeplessness
Ignatia Amara 6X HPUS (0.0000017% Alkaloids, calculated)	anxiousness, worry
Kali Phosphoricum 3X HPUS	wakefulness, occasional sleeplessness, nervousness

"HPUS" indicates that the active ingredients are in the official Homeopathic Pharmacopoeia of the United States.

Uses

- Temporarily relieves symptoms of occasional sleeplessness due to:
- anxiousness ■ worry
- wakefulness ■ nervousness

Warnings

As with any drug, ask a doctor before use if pregnant or breast-feeding.

Do not use more than directed.

Stop use and consult a physician if symptoms persist for more than 7 days or worsen.

Keep this and all medications out of the reach of children.

In case of emergency or accidental overdose, contact a medical professional or Poison Control Center immediately. Hyland's may also be contacted for emergency information about our products 24 hours a day, 7 days per week at (800) 624-9659.

Drug Facts (continued)

Directions

Adults and children 12 years and over: Dissolve 2-3 tablets under tongue at bedtime, then 2-3 tablets every 4 hours during the night as necessary.

Children 6 years to under 12 years: Dissolve 1-2 tablets under tongue at bedtime, then 1-2 tablets every 4 hours during the night as necessary.

Other information

■ **Do not use if imprinted "SEALED FOR YOUR PROTECTION" tamper-evident bottle cap band is broken or missing.**

Inactive ingredients

Acacia Gum, Lactose.

Questions or comments?

(800) 624-9659

***CLAIMS BASED ON TRADITIONAL HOMEOPATHIC PRACTICE, NOT ACCEPTED MEDICAL EVIDENCE. NOT FDA EVALUATED.**

PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Carton

HOMEOPATHIC

NDC 54973-3206-1

SINCE 1903

Hyland's

Sleep*

NATURAL ACTIVE INGREDIENTS
GENTLE ON YOU

Relieves Occasional
Sleeplessness Due
to Nervousness
or Worry

100 QUICK-DISSOLVING TABLETS

*** SEE NOTE ON SIDE PANEL BELOW DRUG FACTS**

NATURAL RELIEF



SLEEP

hyoscyamus niger, strychnos ignatii seed, and potassium phosphate, dibasic tablet

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:54973-3206

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYOSCYAMUS NIGER (UNII: 4WRK2153H3) (HYOSCYAMUS NIGER - UNII:4WRK2153H3)	HYOSCYAMUS NIGER	6 [hp_X]
STRYCHNOS IGNATII SEED (UNII: 1NM3M2487K) (STRYCHNOS IGNATII SEED - UNII:1NM3M2487K)	STRYCHNOS IGNATII SEED	6 [hp_X]
POTASSIUM PHOSPHATE, DIBASIC (UNII: C171S98N1Z) (PHOSPHATE ION - UNII:NK08V8K8HR)	POTASSIUM PHOSPHATE, DIBASIC	3 [hp_X]

Inactive Ingredients

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
LACTOSE (UNII: J2B2A4N98G)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3206-1	1 in 1 CARTON	11/05/2014	
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		11/05/2014	

Labeler - Hyland's Inc. (008316655)

Establishment

Name	Address	ID/FEI	Business Operations
Hyland's Inc.		008316655	manufacture(54973-3206) , pack(54973-3206)