

**BABY NIGHTTIME ORAL PAIN RELIEF- arnica montana, tribasic calcium phosphate, matricaria chamomilla, silicon dioxide, magnesium phosphate, dibasic trihydrate, ferrosferric phosphate, arabica coffee bean and oyster shell calcium carbonate, crude tablet  
HYLAND'S**

*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 Naturals Baby Oral Pain Relief Nighttime**

***Purpose***

Relieves oral discomfort, pain, irritability, swelling and occasional sleeplessness

***Drug Facts***

***Active ingredients***

---

***Active ingredients***

Arnica Montana 30X HPUS  
Calcarea Carbonica 12X HPUS  
Calcarea Phosphorica 12X HPUS  
Chamomilla 12X HPUS  
Coffea Cruda 6X HPUS  
Ferrum Phosphoricum 12X HPUS  
Magnesia Phosphorica 12X HPUS  
Silicea 12X HPUS

***Purpose***

sore, sensitive or swelling gums  
sore, sensitive or swelling gums  
sensitive, swelling gums, oral pain  
sore, sensitive or swelling gums  
oral pain, irritability  
oral discomfort, swelling gums  
oral pain, occasional sleeplessness  
oral pain at night, occasional sleeplessness

---

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

***Uses***

■ Temporarily relieves symptoms of oral pain or discomfort in children at night, including:

- gum sensitivity □■ swelling or soreness of gums
- irritability □ ■ occasional sleeplessness

***Warnings***

**Stop use and ask a doctor if**

■ symptoms persist for more than 72 hours or worsen. ■ swelling increases; nasal congestion, rash or fever is present or develops. ■ irritation, pain or redness persists or worsens.

**Keep out of reach of children.**

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

### ***Directions***

■ Use as directed

---

Children under 6 months	At onset of symptoms, dissolve 2 tablets on tongue every hour up to 4 hours as needed. If symptoms persist, 2 tablets every 4 hours during the night until relieved.
Children 6 months to under 3 years	At onset of symptoms, dissolve 3 tablets on tongue every hour up to 4 hours as needed. If symptoms persist, 3 tablets every 4 hours during the night until relieved

---

### ***Inactive ingredients***

Acacia Gum, Lactose.

### ***Questions?***

[www.hylands.com](http://www.hylands.com) or (800) 624-9659

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

**DO NOT USE IF TAMPER-EVIDENT SEAL IS BROKEN OR MISSING**

### **PACKAGE LABEL**

Hyland's

NATURALS

baby

Oral Pain

Relief

NO BENZOCAINE,  
DYES or PARABENS

Sleeplessness

Teething Pain  
 Oral Discomfort  
 Irritability  
 Swelling

0+ MONTHS

125

QUICK-DISSOLVING TABLETS

HOMEOPATHIC



## BABY NIGHTTIME ORAL PAIN RELIEF

arnica montana, tribasic calcium phosphate, matricaria chamomilla, silicon dioxide, magnesium phosphate, dibasic trihydrate, ferrosferric phosphate, arabica coffee bean and oyster shell calcium carbonate, crude tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54973-3324
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OYSTER SHELL CALCIUM CARBONATE, CRUDE</b> (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	12 [hp_X] in 1 g
<b>TRIBASIC CALCIUM PHOSPHATE</b> (UNII: 91D9GV0Z28) (PHOSPHATE ION - UNII:NK08V8K8HR)	TRIBASIC CALCIUM PHOSPHATE	12 [hp_X] in 1 g
<b>MATRICARIA CHAMOMILLA</b> (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	12 [hp_X] in 1 g
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	12 [hp_X] in 1 g
<b>ARNICA MONTANA</b> (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	30 [hp_X] in 1 g
<b>FERROSFERRIC PHOSPHATE</b> (UNII: 91GQH8I5F7) (FERROSFERRIC PHOSPHATE - UNII:91GQH8I5F7)	FERROSFERRIC PHOSPHATE	12 [hp_X] in 1 g
<b>ARABICA COFFEE BEAN</b> (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	6 [hp_X] in 1 g
<b>MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE</b> (UNII: HF539G9L3Q) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE	12 [hp_X] in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>ACACIA</b> (UNII: 5C5403N26O)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3324-1	1 in 1 CARTON	08/17/2017	
1		1 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:54973-3324-4	6 g in 1 PACKET; Type 0: Not a Combination Product	08/17/2017	12/27/2021

### Marketing Information

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

unapproved homeopathic		08/17/2017	
---------------------------	--	------------	--

**Labeler -** HYLAND'S (028570695)

**Registrant -** STANDARD HOMEOPATHIC COMPANY (HYLAND'S) (008316655)

**Establishment**

Name	Address	ID/FEI	Business Operations
STANDARD HOMEOPATHIC COMPANY		008316655	manufacture(54973-3324) , pack(54973-3324) , label(54973-3324)

**Establishment**

Name	Address	ID/FEI	Business Operations
Standard Homeopathic Company		080253323	manufacture(54973-3324) , pack(54973-3324) , label(54973-3324)

Revised: 12/2021

HYLAND'S