

**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' 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 Naturals Baby Oral Pain Relief Nighttime

Drug Facts

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
teething, sore, sensitive or swelling gums
teething, 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" is the Homeopathic Pharmacopoeia of the United States.

Uses

- Helps temporarily relieve symptoms of oral pain or discomfort in children, including:
- teething ■ 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

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 or care@hylands.com

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

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

Helps temporarily relieve symptoms of oral pain or discomfort in children, including: teething, gum sensitivity, swelling or soreness of gums, irritability, occasional sleeplessness.

Principal Display Panel

Hyland's

NATURALS

•**baby**•

Oral Pain

Relief*

NIGHTTIME

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

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
ACACIA (UNII: 5C5403N26O)	

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:54973-3324-1	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	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
unapproved homeopathic		08/17/2017	

Labeler - Hyland' Inc. (008316655)

Revised: 3/2025

Hyland' Inc.