

**BABY ORAL PAIN RELIEF- oyster shell calcium carbonate, crude, tribasic calcium phosphate, arabica coffee bean, arnica montana, ferrum phosphoricum and matricaria chamomilla 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 Daytime

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

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

"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

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. If symptoms persist,

11 MONTHS	2 tablets every 4 hours until relieved.
Children 6 months to under 3 years	At onset of symptoms, dissolve 3 tablets on tongue every hour up to 4 hours. If symptoms persist, 3 tablets every 4 hours 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

Principal Display Panel

Hyland's

NATURALS™

•baby•

Oral Pain

Relief*

DAYTIME

NO BENZOCAINE,

DYES or PARABENS

Teething Pain

Oral Discomfort

Irritability

Swelling

0+ MONTHS

125

QUICK-DISSOLVING TABLETS

HOMEOPATHIC



BABY ORAL PAIN RELIEF

oyster shell calcium carbonate, crude, tribasic calcium phosphate, arabica coffee bean, arnica montana, ferrum phosphoricum and matricaria chamomilla tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54973-3315
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
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	6 [hp_X] in 1 g
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	30 [hp_X] in 1 g

MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	12 [hp_X] in 1 g
FERRUM PHOSPHORICUM (UNII: 91GQH8I5F7) (FERRUM PHOSPHORICUM - UNII:91GQH8I5F7)	FERRUM PHOSPHORICUM	12 [hp_X] in 1 g

Inactive Ingredients

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

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	5mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3315-1	1 in 1 CARTON	08/17/2017	
1		125 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:54973-3315-3	6 g in 1 PACKET; Type 0: Not a Combination Product	08/17/2017	12/27/2021
3	NDC:54973-3315-7	1 in 1 CARTON	08/17/2017	
3		80 g 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		08/17/2017	

Labeler - Hyland' Inc. (008316655)

Establishment

Name	Address	ID/FEI	Business Operations
Hyland's Inc.		008316655	manufacture(54973-3315) , pack(54973-3315) , label(54973-3315)