

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

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**Baby Daytime Oral Pain Relief**

***Drug Facts***

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<b><i>Active ingredients</i></b>	<b><i>Purpose</i></b>
Arnica Montana 30X HPUS	sore, sensitive or swelling gums
Calcarea Carbonica 12X HPUS	sore, sensitive or swelling gums
Calcarea Phosphorica 12X HPUS	sensitive, swelling gums, oral pain
Chamomilla 12X HPUS	sore, sensitive or swelling gums
Coffea Cruda 6X HPUS	oral pain, irritability
Ferrum Phosphoricum 12X HPUS	oral discomfort, swelling gums

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*“HPUS” indicates that the active ingredients are in the official Homeopathic Pharmacopœia of the United States.*

***Uses***

Temporarily relieves the symptoms of: gum sensitivity, swelling or soreness of gums, oral pain or discomfort.

***Warnings***

**Do not use:** • more than directed. • if your child has a known allergy to any ingredient in this product.

**Consult a physician if:** • symptoms persist for more than 72 hours or worsen. • swelling increases, rash or fever develops. • irritation, pain or redness persists or worsens.

**Keep this and all medications out of the reach of children.** In case of accidental overdose, contact a medical professional or Poison Control Center immediately.

**Do not use if imprinted tamper-evident bottle cap band is broken or missing.**

**The inner packaged bottle is child-resistant.** In case of emergency, 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.

***Directions***

**Children under 6 months of age:** dissolve 1 tablet on tongue every 15 minutes for 4 doses, then hourly until relieved.

**Children 6 months to 3 years of age:** dissolve 2 tablets on tongue every 15 minutes for 4 doses, then hourly until relieved.

Hyland’s Baby Oral Pain Relief Tablets are very soft and will dissolve instantly in the mouth.

***Inactive ingredients***

Acacia Gum, Lactose

***Questions or comments?***

(800) 624-9659.

Relief of pain, irritability and swelling due to oral discomfort

**PRINCIPAL DISPLAY PANEL-125 TABLET BOTTLE CARTON**

NDC 54973-3315-1

**HOMEOPATHIC**

**Natural**

**Relief**

SINCE 1903

*Hyland's*

Baby

Daytime

**Oral Pain**

**Relief\***

RELIEF OF PAIN,

IRRITABILITY, AND SWELLING

DUE TO ORAL DISCOMFORT

No Belladonna, Benzocaine, Artificial Flavors,

Dyes or Parabens

125 QUICK-DISSOLVING TABLETS

ACTUAL SIZE 65 MG



## 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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54973-3315
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
O YSTER SHELL CALCIUM CARBONATE, CRUDE (UNII: 2E32821G61) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G61)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	12 [hp_X] in 1 g
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28) (PHOSPHATE ION -	TRIBASIC CALCIUM	12 [hp_X]

UNII:NK08V8K8HR)	PHOSPHATE	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>ARNICA MONTANA</b> (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	30 [hp_X] in 1 g
<b>MATRICARIA CHAMOMILLA</b> (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	12 [hp_X] in 1 g
<b>FERRUM PHOSPHORICUM</b> (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

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	5mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### 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	
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'S (028570695)

### Establishment

Name	Address	ID/FEI	Business Operations
STANDARD HOMEOPATHIC COMPANY		008316655	manufacture(54973-3315) , pack(54973-3315) , label(54973-3315)

