

**4 KIDS ORAL PAIN RELIEF NIGHTTIME- arnica montana,tribasic calcium phosphate,silicon dioxide,matricaria chamomilla,ferrum phosphoricum,arabica coffee bean,magnesium phosphate, dibasic trihydrate and oyster shell calcium carbonate, crude 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.*

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**4 Kids Oral Pain Relief Nighttime**

**Drug Facts**

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<b>Active Ingredients</b>	<b>Purpose</b>
Arnica Montana 30X HPUS	tooth pain, sensitive or swelling gums
Calcarea Carbonica 12X HPUS	tooth pain, sensitive gums or teeth
Calcarea Phosphorica 12X HPUS	sensitive gums or teeth, oral pain
Chamomilla 12X HPUS	tooth pain, sensitive gums or teeth
Coffea Cruda 6X HPUS	tooth pain, irritability, oral pain
Ferrum Phosphoricum 12X HPUS	tooth pain, oral discomfort, swelling of gums
Magnesia Phosphoricum 12X HPUS	tooth pain, occasional sleeplessness
Silicea 12X HPUS	tooth pain at night, occasional sleeplessness

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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 or tooth sensitivity, swelling of gums, tooth and oral discomfort with occasional sleeplessness.

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

**Do not use** • more than directed • if your child has 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 persist or worsens

**Keep this and all medication 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 band is broken or missing.**

## **In case of an 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 2 years to under 6 years of age:** dissolve 2 tablets on tongue every 15 minutes for 4 doses, then hourly until relieved.

**Children 6 years to under 12 years of age:** dissolve 3 tablets on tongue every 15 minutes for 4 doses, then hourly until relieved.

**Adults and Children 12 years and over:** dissolve 4 tablets on tongue every 15 minutes for 4 doses, then hourly until relieved.

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

Acacia Gum, Lactose

## ***Questions or comments?***

(800) 624-9659.

Oral pain relief

## **PRICIPAL DISPLAY PANEL - 125 TABLET CARTON**

### **New!**

NDC 54973-3325-1

HOMEOPATHIC

### **Natural**

### **Relief**

### **Ages**

**2-12**

SINCE 1903

### ***Hyland's***

4Kids

Oral Pain Relief

### **NIGHTTIME**

Toothache

Sensitive Teeth

Swelling Gums

Oral Discomfort

Occasional Sleeplessness

ACTUAL SIZE 65 MG

125 QUICK-DISSOLVING TABLETS

SAFE & EFFECTIVE



## 4 KIDS ORAL PAIN RELIEF NIGHTTIME

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

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54973-3325
<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>MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE</b> (UNII: HF539G9L3Q) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE	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>FERRUM PHOSPHORICUM</b> (UNII: 91GQH8I5F7) (FERRUM PHOSPHORICUM - UNII:91GQH8I5F7)	FERRUM PHOSPHORICUM	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>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

## Inactive Ingredients

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

## Product Characteristics

<b>Color</b>	white (Of 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:54973-3325-1	1 in 1 CARTON	08/18/2017	
1		125 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:54973-3325-3	6 g in 1 PACKET; Type 0: Not a Combination Product	08/18/2017	12/16/2021

## Marketing Information

<b>Marketing</b>	<b>Application Number or Monograph</b>	<b>Marketing Start</b>	<b>Marketing End</b>
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Category	Citation	Date	Date
unapproved homeopathic		08/18/2017	

**Labeler** - Hyland's Inc. (008316655)

### Establishment

Name	Address	ID/FEI	Business Operations
Hyland's Inc.		008316655	manufacture(54973-3325) , pack(54973-3325) , label(54973-3325)

Revised: 11/2022

Hyland's Inc.