

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

4 Kids Oral Pain Relief

Drug Facts

Active ingredients	Purpose
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
Ferrum Phosphoricum 12X HPUS	tooth pain, oral discomfort, swelling of gums

“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 pain and discomfort.

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

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 band is broken or missing.

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 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 Tablets are very soft and will dissolve instantly in the mouth.
Acacia Gum, Lactose.

Questions or comments?

(800) 624-9659

Oral Pain Relief

PRINCIPAL DISPLAY PANEL - 125 TABLET CARTON**New!**

NDC 54973-3316-1

HOMEOPATHIC**Ages****2-12****Natural****Relief**

SINCE 1903

Hyland's®

4 Kids

Oral Pain Relief

Toothache**Sensitive Teeth****Swelling Gums****Oral Discomfort**

ACTUAL SIZE 65 MG

125 QUICK-DISSOLVING

TABLETS

SAFE &
EFFECTIVE



4 KIDS ORAL PAIN RELIEF

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54973-3316
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
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	6 [hp_X] in 1 g
ARNICA MONTANA (UNII: O80TY208Z W) (ARNICA MONTANA - UNII:O80TY208Z W)	ARNICA MONTANA	30 [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
FERRUM PHOSPHORICUM (UNII: 91GQH8I5F7) (FERRUM PHOSPHORICUM - UNII:91GQH8I5F7)	FERRUM PHOSPHORICUM	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:54973-3316-1	1 in 1 CARTON	08/18/2017	
1		125 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:54973-3316-3	6 g in 1 PACKET; Type 0: Not a Combination Product	08/18/2017	12/16/2021

Marketing Information

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

Labeler - Hyland's Inc. (008316655)

Establishment

Name	Address	ID/FEI	Business Operations
Hyland's Inc.		008316655	manufacture(54973-3316) , pack(54973-3316) , label(54973-3316)

