

**4 KIDS EARACHE RELIEF- matricaria chamomilla, ferric phosphate, sulfur, oyster shell calcium carbonate, crude, lycopodium clavatum spore and anemone pulsatilla 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.

Hyland's 4 Kids Earache Relief

Drug Facts

Active ingredients

Calcarea Carbonica 30C HPUS

Chamomilla 30C HPUS

Ferrum Phosphoricum 30C HPUS

Lycopodium 30C HPUS

Pulsatilla 30C HPUS

Sulphur 30C HPUS

"HPUS" indicates that the active ingredients are in the official Homeopathic Pharmacopœia of the United States.

Purpose

Calcarea Carbonica 30C HPUS.....throbbing ear pain

Chamomilla 30C HPUSoccasional sleeplessness and irritability

Ferrum Phosphoricum 30C HPUS.....minor fever

Lycopodium 30C HPUS.....ear pain

Pulsatilla 30C HPUS.....ear itching, pain worse at night, minor fever

Sulphur 30C HPUS.....ear pain with burning, minor fever

Uses

Temporarily relieves the symptoms of: minor fever, ear pain or throbbing, occasional sleeplessness or irritability associated with earaches after diagnosis by a physician

Warnings

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

Consult a physician if

- symptoms persist for more than 48 hours or worsen. ☐
- discharge from ear is present. ☐
- symptoms are accompanied by a high fever (over 101°F).

Keep this and all medications out of 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 2 years to under 6 years	Dissolve 2 tablets under tongue every 8 hours until relieved for up to 48 hours.
Children 6 years to under 12 years	Dissolve 3 tablets under tongue every 8 hours until relieved for up to 48 hours.
Adults and children 12 years and over	Dissolve 4 tablets under tongue every 8 hours until relieved for up to 48 hours.

Inactive ingredients

Acacia Gum, Lactose.

Questions or comments?

(800) 624-9659

Principal Display Panel - 40 Tablets Bottle Carton

New!

NDC 54973-3393-1

HOMEOPATHIC

Ages

2-12

NATURAL

RELIEF

SINCE 1903

Hyland's

4 Kids

Earache Relief*

Ear Pain

Fever

Irritability

40 QUICK-DISSOLVING TABLETS

ACTUAL SIZE 194 MG



New!

NDC 54973-3393-1
HOMEOPATHIC

**Ages
2-12**



Earache Relief*

Ear Pain
Fever
Irritability



40 QUICK-DISSOLVING TABLETS
ACTUAL SIZE 194 MG

**Package Contains
One Bottle**
Actual Size

**Bottle Contains
40 Tablets**
Actual Size

Manufactured for:
Hyland's, Inc.
Los Angeles, CA 90061
(800) 624-9659
www.hylands.com

Drug Facts

Active ingredients	Purpose
Calcarea Carbonica 30C HPUS.....	throbbing ear pain
Chamomilla 30C HPUS.....	occasional sleeplessness and irritability
Ferrum Phosphoricum 30C HPUS.....	minor fever
Lycopodium 30C HPUS.....	ear pain
Pulsatilla 30C HPUS.....	ear itching, pain worse at night, minor fever
Sulphur 30C HPUS.....	ear pain with burning, minor fever

*"HPUS" indicates that the active ingredients are in the official Homeopathic Pharmacopoeia of the United States.

Uses Temporarily relieves the symptoms of: ■ minor fever ■ ear pain or throbbing ■ occasional sleeplessness or irritability associated with earaches after diagnosis by a physician

Warnings

As with any drug, ask a doctor before use if pregnant or breast-feeding. Consult a physician if: ■ symptoms persist for more than 48 hours or worsen. ■ discharge from ear is present. ■ symptoms are accompanied by a high fever (over 101°F).

Keep this and all medications out of 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 2 years to under 6 years	Dissolve 2 tablets under tongue every 8 hours until relieved for up to 48 hours.
Children 6 years to under 12 years	Dissolve 3 tablets under tongue every 8 hours until relieved for up to 48 hours.
Adults and children 12 years and over	Dissolve 4 tablets under tongue every 8 hours until relieved for up to 48 hours.

Inactive ingredients Acacia Gum, Lactose.

Questions or comments? (800) 624-9659

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

Rev. 001



4 KIDS
EARACHE RELIEF

4 KIDS EARACHE RELIEF

matricaria chamomilla, ferric phosphate, sulfur, oyster shell calcium carbonate, crude, lycopodium clavatum spore and anemone pulsatilla tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54973-3393
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	30 [hp_C]
FERROSFERRIC PHOSPHATE (UNII: 91GQH8I5F7) (FERROSFERRIC PHOSPHATE - UNII:91GQH8I5F7)	FERROSFERRIC PHOSPHATE	30 [hp_C]
LYCOPODIUM CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479)	LYCOPODIUM CLAVATUM SPORE	30 [hp_C]
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	30 [hp_C]
OYSTER SHELL CALCIUM CARBONATE, CRUDE (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	30 [hp_C]
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	30 [hp_C]

Inactive Ingredients

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

Product Characteristics

Color	white (to Off-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:54973-3393-1	1 in 1 CARTON	12/01/2018	
1		40 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			

unapproved homeopathic		12/01/2018	
---------------------------	--	------------	--

Labeler - Hyland's Inc. (008316655)

Establishment

Name	Address	ID/FEI	Business Operations
Hyland's Inc.		008316655	manufacture(54973-3393) , pack(54973-3393) , label(54973-3393)

Revised: 11/2022

Hyland's Inc.