

**BABY TINY COLD DAYTIME AND NIGHTTIME- eupatorium perfoliatum flowering top, euphrasia stricta, gelsemium sempervirens root, potassium iodide, and matricaria recutita 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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**Baby Tiny Cold Tablets Combo Pack**

**DAYTIME**

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
Eupatorium Perfoliatum 6X HPUS	headache, cough, sneezing
Euphrasia Officinalis 6X HPUS	runny eyes/nose
Gelsemium Sempervirens 6X HPUS	sneezing, nasal congestion
Kali Iodatum 6X HPUS	headache, runny eyes/nose

*"HPUS" is the Homeopathic Pharmacopoeia of the United States.*

**Uses**

■ Helps temporarily relieve symptoms of common cold in children, including: ■ runny nose or eyes ■ nasal congestion ■ headache ■ sneezing ■ cough

**Warnings**

**Ask a doctor before use if you have**

■ persistent or chronic cough such as asthma, chronic bronchitis or emphysema. A persistent cough may be a sign of a serious condition. ■ cough that is accompanied by excessive phlegm (mucus).

**Stop use and ask a doctor if**

■ symptoms persist for more than 72 hours or worsen. ■ inflammation, fever or infection is present or develops. ■ cough tends to recur or is accompanied by a fever, rash or persistent headache.

**Keep out of reach of children**

## Directions

■ Use as directed.

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<b>Children under 6 months:</b>	Ask a doctor before use.
<b>Children 6 months to under 1 year:</b>	At onset of symptoms, dissolve 2 tablets on tongue every hour up to 4 hours. If symptoms persist, 2 tablets every 4 hours until relieved.
<b>Children 1 year to under 3 years:</b>	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.

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## Inactive ingredients

Acacia Gum, Lactose.

## NIGHTTIME

### Drug Facts

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<b>Active ingredients</b>	<b>Purpose</b>
Chamomilla 6X HPUS	occasional sleeplessness
Eupatorium Perfoliatum 6X HPUS	headache, cough, sneezing
Euphrasia Officinalis 6X HPUS	runny eyes/nose, nighttime coughing
Gelsemium Sempervirens 6X HPUS	sneezing, nasal congestion
Kali Iodatum 6X HPUS	headache, runny eyes/nose

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"HPUS" is the Homeopathic Pharmacopoeia of the United States.

## Uses

■ Helps temporarily relieve symptoms of common cold in children at night, including:  
■ runny nose or eyes ■ cough ■ nasal congestion  
■ headache ■ sneezing ■ occasional sleeplessness

## NIGHTTIME

### Drug Facts (continued)

## Warnings

## Ask a doctor before use if you have

■ persistent or chronic cough such as asthma, chronic bronchitis or emphysema. A persistent cough may be a sign of a serious condition. ■ cough that is accompanied by excessive phlegm (mucus).

## Stop use and ask a doctor if

■ symptoms persist for more than 72 hours or worsen. ■ inflammation, fever or infection is present or develops. ■ cough tends to recur or is accompanied by a fever, rash or persistent headache.

## Keep out of reach of children

## Directions

■ Use as directed

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<b>Children under 6 months:</b>	Ask a doctor before use.
<b>Children 6 months to under 1 year:</b>	At onset of symptoms, dissolve 2 tablets on tongue every hour up to 4 hours as needed. If symptoms persist, 2 tablets every 4 hours during the night until relieved.
<b>Children 1 year to under 3 years:</b>	At onset of symptoms, dissolve 3 tablets on tongue every hour up to 4 hours as needed. If symptoms persist, 3 tablets every 4 hours during the night until relieved.

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## Inactive ingredients

Acacia Gum, Lactose.

## Questions?

[www.hylands.com](http://www.hylands.com) or [care@hylands.com](mailto: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 common cold in children at night, including: runny nose or eyes, cough, nasal congestion, headache, sneezing, occasional sleeplessness.

## Principal Display Panel

**Hyland's**

NATURALS

•baby•

**Tiny Cold Tablets\***

COMBO PACK

**NO ARTIFICIAL FLAVORS, PARABENS or DYES**

**DAYTIME**

Nasal Congestion

Runny Nose

Sneezing

Cough

**NIGHTTIME**

Sleeplessness

Nasal Congestion

Runny Nose

Sneezing

Cough

**6+ MONTHS**

2 x 125 CT BOTTLES

(1 DAY, 1 NIGHT)

QUICK-DISSOLVING TABLETS

HOMEOPATHIC



## BABY TINY COLD DAYTIME AND NIGHTTIME

eupatorium perfoliatum flowering top, euphrasia stricta, gelsemium sempervirens root, potassium iodide, and matricaria recutita kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54973-3307
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3307-1	1 in 1 CARTON	01/11/2017	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
<b>Part 1</b>	1 BOTTLE, PLASTIC	125
<b>Part 2</b>	1 BOTTLE, PLASTIC	125

## Part 1 of 2

### TINY COLD

eupatorium perfoliatum flowering top, euphrasia stricta, gelsemium sempervirens root, and potassium iodide tablet, soluble

#### Product Information

**Item Code (Source)** NDC:54973-3158

**Route of Administration** ORAL

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>EUPATORIUM PERFOLIATUM FLOWERING TOP</b> (UNII: 1W0775VX6E) (EUPATORIUM PERFOLIATUM FLOWERING TOP - UNII:1W0775VX6E)	EUPATORIUM PERFOLIATUM FLOWERING TOP	6 [hp_X]
<b>EUPHRASIA STRICTA</b> (UNII: C9642I91WL) (EUPHRASIA STRICTA - UNII:C9642I91WL)	EUPHRASIA STRICTA	6 [hp_X]
<b>GELSEMIUM SEMPERVIRENS ROOT</b> (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	6 [hp_X]
<b>POTASSIUM IODIDE</b> (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	POTASSIUM IODIDE	6 [hp_X]

#### Inactive Ingredients

Ingredient Name	Strength
<b>LACTOSE, UNSPECIFIED FORM</b> (UNII: J2B2A4N98G)	
<b>ACACIA</b> (UNII: 5C5403N26O)	

#### 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:54973-3158-1	1 in 1 CARTON		
1		125 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		12/28/2015	

## Part 2 of 2

### BABY NIGHTTIME TINY COLD

matricaria recutita, eupatorium perfoliatum flowering top, euphrasia stricta, gelsemium sempervirens root, and potassium iodide tablet

## Product Information

Item Code (Source)	NDC:54973-3252
Route of Administration	ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MATRICARIA RECUTITA</b> (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	6 [hp_X]
<b>EUPATORIUM PERFOLIATUM FLOWERING TOP</b> (UNII: 1W0775VX6E) (EUPATORIUM PERFOLIATUM FLOWERING TOP - UNII:1W0775VX6E)	EUPATORIUM PERFOLIATUM FLOWERING TOP	6 [hp_X]
<b>EUPHRASIA STRICTA</b> (UNII: C9642I91WL) (EUPHRASIA STRICTA - UNII:C9642I91WL)	EUPHRASIA STRICTA	6 [hp_X]
<b>GELSEMIUM SEMPERVIRENS ROOT</b> (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	6 [hp_X]
<b>POTASSIUM IODIDE</b> (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	POTASSIUM IODIDE	6 [hp_X]

## Inactive Ingredients

Ingredient Name	Strength
<b>ACACIA</b> (UNII: 5C5403N26O)	
<b>LACTOSE, UNSPECIFIED FORM</b> (UNII: J2B2A4N98G)	

## 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
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1	NDC:54973-3252-1	1 in 1 CARTON		
1		125 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		12/28/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		01/11/2017	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Hyland's Inc		008316655	manufacture(54973-3307) , pack(54973-3307) , label(54973-3307)

Revised: 11/2022

Hyland's Inc.