

**BABY NIGHTTIME TINY COLD- chamomile, eupatorium perfoliatum flowering top, euphrasia stricta, gelsemium sempervirens root, and potassium iodide liquid  
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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**Hyland's Naturals Baby Tiny Cold Syrup 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 and nose
Gelsemium Sempervirens 6X HPUS	sneezing with stuffy nose
Kali Iodatum 6X HPUS	headache, runny eyes and nose

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

**Uses**

- Temporarily relieves symptoms of common cold in children at night, including: ■ runny nose or eyes ■ cough ■ nasal congestion
- headache ■ sneezing ■ occasional sleeplessness

**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. □ Do not refrigerate. ■ Shake well before using. ■ Measure only with the dosing syringe provided. ■ Do not use dosing syringe with other products. ■ On dosing syringe, mL = milliliter.

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Children under 6 months	Ask a doctor before use.
Children 6 months to under 1 year	2.5 mL at bedtime and every 6 hours during the night until relieved.
Children 1 year to under 3 years	5 mL at bedtime and every 4 hours during the night until relieved.

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## **Inactive ingredients**

Citric Acid, Glycerine, Glycyrrhiza Extract, Purified Water, Sodium Benzoate.

## **Questions?**

(800) 624-9659

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

**DO NOT USE IF TAMPER-EVIDENT SEAL IS BROKEN OR MISSING.**

**PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton**

**Hyland's**

NATURALS

•baby•

**Tiny Cold**

**Syrup**

NIGHTTIME

NO ALCOHOL, SUGAR,

PARABENS or DYES

Sleeplessness

Congestion

Runny Nose

Sneezing

6+ MONTHS

4 FL. OZ. (118 mL)

HOMEOPATHIC



**Drug Facts**

**Active Ingredients** Purpose  
Chamomilla BX HPUS ..... occasional sleeplessness  
Eupatorium Perfoliatum BX HPUS ..... headache, cough, sneezing  
Euphrasia Officinalis BX HPUS ..... runny eyes/nose, nighttime coughing  
Gelsemium Sempervirens BX HPUS ..... sneezing, nasal congestion  
Kali Iodatum BX HPUS ..... headache, runny eyes/nose  
\*HPUS\* is the Homeopathic Pharmacopoeia of the United States.

**Uses**

Temporarily relieves symptoms of common cold in children at night, including:  
runny nose or eyes cough nasal congestion  
headache sneezing occasional sleeplessness

**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. Do not refrigerate. Shake well before using. Measure only with the dosing syringe provided. Do not use dosing syringe with other products. On dosing syringe, mL = milliliter.

Children under 6 months Ask a doctor before use.

Children 6 months to under 1 year 2.5 mL at bedtime and every 6 hours during the night until relieved.

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**Inactive Ingredients** Citric Acid, Glycerine, Glycyrrhiza Extract, Purified Water, Sodium Benzoate.

**Questions?** (800) 624-8659

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Manufactured for:  
Hyland's, Inc.  
Los Angeles, CA 90061  
www.hylands.com



REV. 001

## BABY NIGHTTIME TINY COLD

chamomile, eupatorium perfoliatum flowering top, euphrasia stricta, gelsemium sempervirens root, and potassium iodide liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54973-3180
<b>Route of Administration</b>	ORAL		

<b>Active Ingredient/Active Moiety</b>		
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>CHAMOMILE</b> (UNII: FGL3685T2X) (CHAMOMILE - UNII:FGL3685T2X)	CHAMOMILE	6 [hp_X] in 1 mL
<b>EUPATORIUM PERFOLIATUM FLOWERING TOP</b> (UNII: 1W0775VX6E) (EUPATORIUM PERFOLIATUM FLOWERING TOP - UNII:1W0775VX6E)	EUPATORIUM PERFOLIATUM FLOWERING TOP	6 [hp_X] in 1 mL
<b>EUPHRASIA STRICTA</b> (UNII: C9642I91WL) (EUPHRASIA STRICTA - UNII:C9642I91WL)	EUPHRASIA STRICTA	6 [hp_X] in 1 mL
<b>GELSEMIUM SEMPERVIRENS ROOT</b> (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	6 [hp_X] in 1 mL
<b>POTASSIUM IODIDE</b> (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	6 [hp_X] in 1 mL

<b>Inactive Ingredients</b>	
<b>Ingredient Name</b>	<b>Strength</b>
<b>GLYCYRRHIZA GLABRA</b> (UNII: 2788Z9758H)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:54973-3180-1	1 in 1 CARTON	07/01/2014	
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:54973-3180-2	5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2014	12/27/2021
3	NDC:54973-3180-3	19.8 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2014	12/27/2021

<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
unapproved homeopathic		07/01/2014	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Hyland's Inc.		008316655	manufacture(54973-3180) , pack(54973-3180)

## Establishment

Name	Address	ID/FEI	Business Operations
LGM Pharma Solutions, LLC		117549198	manufacture(54973-3180) , pack(54973-3180) , label(54973-3180)

Revised: 11/2022

Hyland's Inc.