

**INFANTS TEETHING- chamomilla, calcarea phosphorica, coffea cruda, belladonna tablet, orally disintegrating
CVS PHARMACY**

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.

Drug Facts

Active ingredients HPUS

Chamomilla 6X

Calcarea phosphorica 6X

Coffea cruda 6X

Belladonna 12X (calculated as 0.0000000000003% alkaloids)

*The letters "HPUS" indicate that the components in this product are officially monographed in the Homoeopathic Pharmacopoeia of the United States.

Purpose

Irritability

Teething, dentition

Sleeplessness

Redness and pain

Uses

Temporarily relieves the symptoms of simple restlessness and wakeful irritability due to cutting teeth. Helps reduce gum redness and pain.

*These claims have not been reviewed by the Food and Drug Administration. They are based on traditional homeopathic practice.

Warnings

As with any drug, ask a doctor before use if pregnant or nursing.

Stop use and ask a doctor if:

- symptoms do not improve in 7 days
- swelling, rash or fever develops
- irritation, pain and redness worsens.

Keep this and all medications out of the reach of children.

In case of emergency or accidental overdose, contact a medical professional or a poison control center immediately.

Do not use

- more often than directed
- for more than 7 days in a row unless directed by a doctor or dentist
- if your child has a known allergy to any ingredient in this product.

Do not use if security seal is broken or missing.

Directions

Allow 2 or 3 tablets to dissolve under the tongue 4 times a day, or as directed by a licensed health care professional. If the child is restless or wakeful, allow 2 tablets to dissolve under the tongue every hour for 6 doses, or as directed by a licensed health care professional. If preferred, tablets may be dissolved in a teaspoon of water and then given to the child. CVS/pharmacy Teething Tablets are very soft and will dissolve almost instantly in the mouth. Please note: if your child has been crying or is upset, your child may fall asleep after using this product because the pain has been relieved and your child can rest.

Other information

Store at room temperature (68°-77°F)

Inactive ingredients

Dextrose, maltodextrin, corn starch, crospovidone, magnesium stearate, lactose.

<p>RETAIN CARTON FOR COMPLETE INSTRUCTIONS</p> <p>Drug Facts</p> <p>Active ingredients HPUS:</p> <table border="0"> <tr> <td>Chamomilla 6X.....</td> <td>Irritability</td> </tr> <tr> <td>Calcarea phosphorica 6X.....</td> <td>Teething, dentition</td> </tr> <tr> <td>Coffea cruda 6X.....</td> <td>Sleeplessness</td> </tr> <tr> <td>Belladonna 12X.....</td> <td>Redness and pain (calculated as 0.0000000000003% alkaloids)</td> </tr> </table> <p>The letters 'HPUS' indicate that the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the United States.</p> <p>Uses</p> <p>Temporarily relieves the symptoms of simple restlessness and wakeful irritability due to cutting teeth. Helps reduce gum redness and pain.</p> <p>Warnings</p> <p>As with any drug, ask a doctor before use if pregnant or nursing. Stop use and ask a doctor if: ■ symptoms do not improve in 7 days ■ swelling, rash or fever develops ■ irritation, pain or redness persists or worsens.</p> <p>Keep this and all medications out of the reach of children. In case of emergency or accidental overdose, contact a medical professional or a poison control center immediately.</p> <p>Do not use: ■ more often than directed ■ for more than 7 days in a row unless directed by a doctor or dentist ■ if your child has a known allergy to any ingredient in this product</p> <p>Do not use if security seal is broken or missing.</p> <p>Directions</p> <p>Allow 2 or 3 tablets to dissolve under the tongue 4 times a day, or as directed by a licensed health care professional. If the child is restless or wakeful, allow 2 tablets to dissolve under the tongue every hour for 6 doses, or as directed by a licensed health care professional. If preferred, tablets may be dissolved in a teaspoon of water and then given to the child. CVS/pharmacy™ Teething Tablets are very soft and will dissolve almost instantly in the mouth. Please note: if your child has been crying or is upset, your child may fall asleep after using this product because the pain has been relieved and your child can rest.</p> <p>Other information</p> <p>■ Store at room temperature (68° – 77°F).</p> <p>Inactive ingredients</p> <p>Dextrose, maltodextrin, corn starch, crospovidone, magnesium stearate, lactose.</p> <p><small>*These claims have not been reviewed by the Food and Drug Administration. They are based on traditional homeopathic practice.</small></p>	Chamomilla 6X.....	Irritability	Calcarea phosphorica 6X.....	Teething, dentition	Coffea cruda 6X.....	Sleeplessness	Belladonna 12X.....	Redness and pain (calculated as 0.0000000000003% alkaloids)	<p>CVS Pharmacy™</p> <p>Homeopathic INFANTS' TEETHING TABLETS</p> <p>NATURAL RELIEF OF PAIN & IRRITABILITY DUE TO TEETHING*</p> <p>Distributed by: CVS Pharmacy, Inc. One CVS Drive Woonsocket, RI 02895 © 2014 CVS/pharmacy CVS.com® 1-800-SHOP CVS</p> <p>Made in USA V-30496</p> <p>Please Recycle</p> <p>CVS® Quality Money Back Guarantee</p>	<p>CVS Pharmacy™</p> <p>NDC 59779-860-03</p> <p>NEW! For Ages 0-3</p> <p>Homeopathic INFANTS' TEETHING TABLETS</p> <p>NATURAL RELIEF OF PAIN & IRRITABILITY DUE TO TEETHING*</p> <p>■ Soft tablets dissolve instantly</p> <p>■ No artificial flavors, dyes or parabens</p> <p>135 QUICK-DISSOLVING TABLETS</p>	<p>CVS Pharmacy™</p> <p>Homeopathic INFANTS' TEETHING TABLETS</p> <p>NATURAL RELIEF OF PAIN & IRRITABILITY DUE TO TEETHING*</p> <p>CVS/pharmacy™ Homeopathic Teething Tablets provide natural relief of pain and irritability caused by teething. These soft tablets dissolve instantly and are made without artificial flavors, dyes or parabens.</p>
Chamomilla 6X.....	Irritability										
Calcarea phosphorica 6X.....	Teething, dentition										
Coffea cruda 6X.....	Sleeplessness										
Belladonna 12X.....	Redness and pain (calculated as 0.0000000000003% alkaloids)										
<p># 968765 UPC 0 50428 48333 6 Lot: Exp:</p>											

chamomilla, calcarea phosphorica, coffea cruda, belladonna tablet, orally disintegrating

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-860
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHAMOMILE (UNII: FGL3685T2X) (CHAMOMILE - UNII:FGL3685T2X)	CHAMOMILE	6 [hp_X]
CALCIUM PHOSPHATE (UNII: 97Z1W3NDX) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	6 [hp_X]
COFFEA ARABICA FRUIT (UNII: HOX6BEK27Q) (COFFEA ARABICA FRUIT - UNII:HOX6BEK27Q)	COFFEA ARABICA FRUIT	6 [hp_X]
ATROPA BELLADONNA WHOLE (UNII: DSV74G1P2J) (ATROPA BELLADONNA WHOLE - UNII:DSV74G1P2J)	ATROPA BELLADONNA WHOLE	12 [hp_X]

Inactive Ingredients

Ingredient Name	Strength
DEXTROSE (UNII: IY9XDZ35W2)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE (UNII: 68401960MK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

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
1	NDC:59779-860-03	135 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		02/14/2014	

Labeler - CVS PHARMACY (062312574)

Registrant - HOMEOLAB USA INC. (202032533)

Establishment

Name	Address	ID/FEI	Business Operations
HOMEOLAB USA INC.		202032533	manufacture(59779-860)

Revised: 2/2014

CVS PHARMACY