

CHILDREN COLDCALM- onion, apis mellifera, atropa belladonna, eupatorium perfoliatum flowering top, gelsemium sempervirens root, potassium dichromate, strychnos nux-vomica seed, phytolacca americana root, pulsatilla vulgaris pellet
Laboratoires Boiron

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.

ColdCalm Kids

Allium cepa 3C HPUS (0.049.mg)**

Apis mellifica 6C HPUS (0.049mg)**

Belladonna 6C HPUS (0.049mg)** (contains less than 10^{-15} mg atropine alkaloids.

Eupatorium perfoliatum 3C (0.049mg)**

Gelsemium sempervirens 6C (0.049mg)** (contains less an 10^{-15} mg gelsemine alkaloids)

Kali bichromicum 6C (0.049mg)** (contains less than 10^{-13} mg chromium)

Nux vomica 3C (0.049mg)** (contains less than 10^{-8} mg strychnine alkaloids)

Phytolacca decandra 6C (0.049mg)**

Pulsatilla 6C (0.049mg)**

(in each pellet)

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

Allium cepa 3C HPUS (0.049.mg)* ... Relieves sneezing and runny nose

Apis mellifica 6C HPUS (0.049mg)* ... Relieves nasal congestion

Belladonna 6C HPUS (0.049mg)* ... Relieves colds with a sudden onset

Eupatorium perfoliatum 3C (0.049mg)* ... Relieves body aches associated with colds

Gelsemium sempervirens 6C (0.049mg)* ... Relieves body aches associated with colds

Kali bichromicum 6C (0.049mg)* ... Relieves nasal discharge

Nux vomica 3C (0.049mg)* ... Relieves sneezing attacks

Phytolacca decandra 6C (0.049mg)* ... Relieves minor sore throat associated with colds

Pulsatilla 6C (0.049mg)* ... Relieves colds with a loss of taste and smell

Temporary relieves cold symptoms such as sneezing, runny nose, nasal congestion and minor sore throat.

Lactose, Sucrose.

2 Tubes Approx. 80 pellets each, 3.8g (0.133 oz.) 16 doses per tube Total 160 Pellets

ColdCalm.com

www.boironusa.com

1-800-BOIRON-1

Made in France

Distributed by Boiron, Inc.
Newtown Square, PA
19073-3267

Ask a doctor before use if sore throat is severe, accompanied or followed by a fever, headache, rash, nausea or vomiting.

Stop use and ask a doctor if symptoms persist for more than 2 days or worsen, or if new symptom occur.

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Do not use if glued carton end flaps are open or if pellet dispenser seal is broken.

Children 3 years of age and older: At the onset of symptoms, dissolve 5 pellets under the tongue every 15 minutes for 1 hour. Then, take 5 pellets every 6 hours. Decrease frequency with improvement.

Children under 3 years of age: Ask a doctor.

Turn tube upside down, twist until 5 pellets are dispensed, remove cap and pour pellets under the tongue.

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

*C,K,CK, and X are homeopathic dilutions: see BoironUSA.com/info for details.





Peel for Drug Facts and Directions.

13 oz)

cap.

Drug Facts

Active ingredients

Purpose

Allium cepa 3C HPUS.....Relieves sneezing and runny nose

Apis mellifica 6C HPUS.....Relieves nasal congestion

Belladonna 6C HPUS.....Relieves colds with a sudden onset

Eupatorium perfoliatum 3C HPUS.....Relieves body aches associated with colds

Gelsemium sempervirens 6C HPUS.....Relieves headaches associated with colds

Kali bichromicum 6C HPUS.....Relieves nasal discharge

Nux vomica 3C HPUS.....Relieves sneezing attacks

Phytolacca decandra 6C HPUS.....Relieves minor sore throat associated with colds

Pulsatilla 6C HPUS.....Relieves colds with a loss of taste and smell

Uses temporarily relieves cold symptoms such as: ■ sneezing
■ runny nose ■ nasal congestion ■ minor sore throat

Warnings

Ask a doctor before use if sore throat is severe, accompanied or followed by fever, headache, rash, nausea, or vomiting.

Stop use and ask a doctor if symptoms persist for more than 2 days or worsen, or if new symptoms occur.

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions

■ Children 3 years of age and older: At the onset of symptoms, dissolve 5 pellets under the tongue every 15 minutes for 1 hour. Then, take 5 pellets every 6 hours. Decrease frequency with improvement.

■ Children under 3 years of age: Ask a doctor.

Other information do not use if glued carton end flaps are open or if pellet dispenser seal is broken

Inactive ingredients lactose, sucrose

NDC 0220-90144-42



3+ YEARS

COLD RELIEF*

Sneezing • Runny Nose
Nasal Congestion



ColdCalm[®] kids MELTAWAY PELLETS

HOMEOPATHIC MEDICINE

- No Known Drug Interactions
- Non-Drowsy
- Kid-Friendly Taste



BOIRON
World Leader in Homeopathic Medicines

2 TUBES
APPROX. 80 PELLETS EACH
TOTAL 160 PELLETS

- Turn tube upside down
- Twist until 2 pellets are exposed
- Remove cap and give pellets to child. For storage, recap.



The Boiron Promise
Your health deserves the greatest respect. That's why we're committed to your satisfaction. Please visit BoironUSA.com/promise for details.

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

Directions of use: <i>See back of box for directions.</i>
Warnings: <i>See back of box for warnings.</i>
Directions: <i>See back of box for directions.</i>
Other information: <i>See back of box for other information.</i>
Active ingredients: <i>See back of box for active ingredients.</i>
Proprietary: <i>See back of box for proprietary information.</i>
Drug Facts: <i>See back of box for drug facts.</i>
Purpose: <i>See back of box for purpose.</i>

Manufactured by Boiron, Inc.
Nutley, NJ 07110

Children's ColdCalm®

Drug Facts

Active ingredients** (in each pellet)

Allium cepa 3C (0.045 mg)	Relieves sneezing and runny nose
Apis mellifica 6C (0.045 mg)	Relieves nasal congestion
Belladonna 6C (0.045 mg)	Relieves colds with a sudden onset (contains less than 10 ⁻⁶ mg alkaloids per pellet)
Eupatorium perfoliatum 3C (0.045 mg)	Relieves body aches associated with colds
Gelsemium sempervirens 6C (0.045 mg)	Relieves headaches associated with colds
Kali bichromicum 6C (0.045 mg)	Relieves nasal discharge
Nux vomica 3C (0.045 mg)	Relieves sneezing attacks (contains less than 10 ⁻⁶ mg strychnine per pellet)
Phytolacca decandra 6C (0.045 mg)	Relieves minor sore throat associated with colds
Pulsatilla 6C (0.045 mg)	Relieves colds with a loss of taste and smell

The letters "C" and "X" indicate that the components in this product are officially recognized in the Homeopathic Pharmacopoeia of the United States.

Uses* temporarily relieves cold symptoms such as:

- sneezing
- runny nose
- nasal congestion
- minor sore throat

Warnings
 Stop use and ask a doctor if symptoms persist for more than 2 days or worsen, or if sore throat is severe, persistent, or accompanied by high fever, headache, nausea, and vomiting. These may be signs of a serious condition.

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions ■ Children 3 years of age and older: At the onset of symptoms, dissolve 5 pellets under the tongue every 15 minutes for 1 hour. Then, dissolve 5 pellets under the tongue 3 times a day until symptoms are relieved. ■ Children under 3 years of age: Ask a doctor.

Other information do not use if pellet dispenser seal is broken

Inactive ingredients lactose, sucrose

Questions or comments?
 ColdCalm.com BoironUSA.com Info@Boiron.com 1-800-BOIRON-1 (1-800-264-7801)

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

**C, X, CK, and X are homeopathic dilutions. See BoironUSA.com/info for details.



Distributed by Boiron Inc., Newtown Square, PA 19073

Made in France please recycle

3 06969 04942 4

How to dispense pellets?

Turn tube upside down.



Twist and pull up as directed.



Carefully remove pellets as they fall into the tube.



NDC 0220-9049-42

children's COLD RELIEF®

Sneezing • Runny Nose • Nasal Congestion • Minor Sore Throat*

ColdCalm®

Non-Drowsy • No Known Drug Interactions



HOMEOPATHIC MEDICINE



help your body use the NATURAL way

BOIRON®

World Leader in Homeopathic Medicines

2 TUBES APPROX. 80 QUICK-DISSOLVING PELLETS PER TUBE

children's ColdCalm® Take at the First Sign of Cold Symptoms*

HOMEOPATHIC MEDICINE

children's ColdCalm®

Drug Facts **Active ingredients**** Allium cepa 3C, Apis mellifica 6C, Belladonna 6C (contains less than 10⁻⁶ mg alkaloids per pellet), Eupatorium perfoliatum 3C, Gelsemium sempervirens 6C, Kali bichromicum 6C, Nux vomica 3C (contains less than 10⁻⁶ mg strychnine per pellet), Phytolacca decandra 6C, Pulsatilla 6C **Uses*** temporarily relieves cold symptoms such as: ■ sneezing ■ runny nose ■ nasal congestion ■ minor sore throat **Warnings** Stop use and ask a doctor if symptoms persist for more than 2 days or worsen, or if sore throat is severe, persistent, or accompanied by high fever, headache, nausea, and vomiting. These may be signs of a serious condition. Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away. **Directions** ■ Children 3 years of age and older: At the onset of symptoms, dissolve 5 pellets under the tongue every 15 minutes for 1 hour. Then, dissolve 5 pellets under the tongue 3 times a day until symptoms are relieved. ■ Children under 3 years of age: Ask a doctor. **Other information** do not use if pellet dispenser seal is broken **Inactive ingredients** lactose, sucrose **Contents** Approx. 80 pellets, 3.8 g (0.133 oz)

ETI-10YK *CLAIMS BASED ON TRADITIONAL HOMEOPATHIC PRACTICE, NOT ACCEPTED MEDICAL EVIDENCE. NOT FDA EVALUATED.

**C, X, CK, and X are homeopathic dilutions. See BoironUSA.com/info for details.

Lot Exp.

Distributed by Boiron Inc.
 Made in France
 NDC 0220-9049-41

BOIRON®

BoironUSA.com
 Info@Boiron.com

Turn tube upside down & twist cap



children's ColdCalm
HOMEOPATHIC MEDICINE

Developed by Boiron Inc.
 Made in France
 NDC 0220-9049-41

BOIRON
 www.BoironUSA.com
 info@Boiron.com
 Turn tube upside down & twist cap
 Pull here

Drug Facts **Active ingredients:** Allium cepa 3C, Apis mellifica 6C, Belladonna 6C, Eupatorium perfoliatum 3C, Gelsemium sempervirens 6C, Kali bichromicum 6C, Nux vomica 3C, Phytolacca decandra 6C, Pulsatilla 6C (contains less than 10th mg alkaloids per dose) **Uses*** Temporarily relieves cold symptoms such as: ■ sneezing ■ runny nose ■ nasal congestion ■ minor sore throat **Warnings** Ask a doctor before use in children under 3 years of age. Stop use and ask a doctor if symptoms persist for more than 3 days or worsen, or if sore throat persists for more than 2 days or occurs with a fever, headache, rash, nausea or vomiting. **Keep out of reach of children.** **Directions** ■ Children 3 years of age and older: At the onset of symptoms, dissolve 5 pellets under the tongue every 15 minutes for 1 hour. Then, dissolve 5 pellets under the tongue every 2 hours until symptoms are relieved. ■ Children under 3 years of age: Ask a doctor. **Other information** Do not use if the label sealing the clear tube cap is broken or missing. Store at Lot Expiration Date 68-77°F (20-25°C). **Inactive ingredients** Lactose, sucrose **Contents** Approx. 80 pellets, 3.8 g (0.133 oz)

*These "Uses" have not been evaluated by the FDA.

Children's ColdCalm

Drug Facts

Active ingredients**	Purpose*
Allium cepa 3C HPUS	Relieves sneezing and runny nose
Apis mellifica 6C HPUS	Relieves nasal congestion
Belladonna 6C HPUS	Relieves colds with a sudden onset (contains less than 10 th mg alkaloids per dose)
Eupatorium perfoliatum 3C HPUS	Relieves body aches associated with colds
Gelsemium sempervirens 6C HPUS	Relieves headaches associated with colds
Kali bichromicum 6C HPUS	Relieves nasal discharge
Nux vomica 3C HPUS	Relieves sneezing attacks (contains less than 10 th mg alkaloids per dose)
Phytolacca decandra 6C HPUS	Relieves minor sore throat associated with colds
Pulsatilla 6C HPUS	Relieves colds with a loss of taste and smell

The letters HPUS indicate that this ingredient is officially included in the Homeopathic Pharmacopoeia of the United States.

Uses* ■ temporarily relieves cold symptoms such as: ■ sneezing ■ runny nose ■ nasal congestion ■ minor sore throat

Warnings Ask a doctor before use in children under 3 years of age. Stop use and ask a doctor if symptoms persist for more than 2 days or worsen, or if sore throat is severe or persistent or it occurs with a high fever, headache, rash, nausea and vomiting. This may be a sign of a more serious condition. **Keep out of reach of children.**

Directions ■ Children 3 years of age and older: At the onset of symptoms, dissolve 5 pellets under the tongue every 15 minutes for 1 hour. Then, dissolve 5 pellets under the tongue 3 times a day until symptoms are relieved. ■ Children under 3 years of age: Ask a doctor.

Other information ■ do not use if pellet dispenser seal is broken

Inactive ingredients lactose, sucrose

Questions or comments?
 ColdCalm.com BoironUSA.com
 Info@Boiron.com
 1-800-BOIRON-1 (1-800-264-7661)
 Distributed by Boiron Inc., 6 Campus Boulevard, Newtown Square, PA 19073-3267

*These "Uses" have not been evaluated by the Food and Drug Administration.
 **C, K, CK, and X are homeopathic dilutions: see BoironUSA.com for details.

Made in France
 please recycle

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children's ColdCalm

children's GOLD RELIEF*
 Sneezing • Runny Nose • Nasal Congestion • Minor Sore Throat*

ColdCalm
 Non-Drowsy • No Known Drug Interactions

HOMEOPATHIC MEDICINE

help your body the NATURAL way

BOIRON
 World Leader in Homeopathic Medicines

2 TUBES APPROX. 80 QUICK-DISSOLVING PELLETS PER TUBE

3+ and older

Take at the Onset of Cold Symptoms

How to dispense pellets?

- 1 Turn tube upside down.
- 2 Twist until 5 pellets are dispensed into cap.
- 3 Carefully remove cap and use it to pour pellets under the tongue.

NDC 0220-9049-42

CHILDREN COLDCALM

onion, apis mellifera, atropa belladonna, eupatorium perfoliatum flowering top, gelsemium sempervirens root, potassium dichromate, strychnos nux-vomica seed, phytolacca americana root, pulsatilla vulgaris pellet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0220-9049
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ONION (UNII: 492225Q21H) (ONION - UNII:492225Q21H)	ONION	3 [hp_C]
APIS MELLIFERA (UNII: 7S82P3R43Z) (APIS MELLIFERA - UNII:7S82P3R43Z)	APIS MELLIFERA	5 [hp_C]
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	6 [hp_C]
EUPATORIUM PERFOLIATUM FLOWERING TOP (UNII: 1W0775VX6E) (EUPATORIUM PERFOLIATUM FLOWERING TOP - UNII:1W0775VX6E)	EUPATORIUM PERFOLIATUM FLOWERING TOP	3 [hp_C]
GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	6 [hp_C]
POTASSIUM DICHROMATE (UNII: T4423S18FM) (DICHROMATE ION - UNII:9LKY4BFN2V)	POTASSIUM DICHROMATE	6 [hp_C]
STRYCHNOS NUX-VOMICA SEED (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	3 [hp_C]
PHYTOLACCA AMERICANA ROOT (UNII: 11E6VI8VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6VI8VEG)	PHYTOLACCA AMERICANA ROOT	6 [hp_C]
PULSATILLA VULGARIS (UNII: I76KB35JEV) (PULSATILLA VULGARIS - UNII:I76KB35JEV)	PULSATILLA VULGARIS	6 [hp_C]

Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	
LACTOSE (UNII: J2B2A4N98G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0220-9049-42	1 in 1 BOX	09/08/2008	
1	NDC:0220-9049-41	80 in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		09/08/2008	

Labeler - Laboratoires Boiron (282560473)

Registrant - Boiron Inc. (014892269)

Establishment

Name	Address	ID/FEI	Business Operations
Boiron		282560473	manufacture(0220-9049)