

EARACHE- belladonna, calcarea carbonica, chamomilla, lycopodium clavatum, pulsatilla (vulgaris), sulphur liquid
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:

Belladonna 30C HPUS.....Temperature above normal

Calcarea Carbonica 30C HPUS.....Burning Ear

Chamomilla 30C HPUS.....Sleeplessness and irritability

Lycopodium Clavatum 30C HPUS.....Ear discomfort

Pulsatilla (Vulgaris) 30C HPUS.....Ear itching, discomfort at night

Sulphur 30C HPUS.....Throbbing ear

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

USES*:

• **For use in the ears only.** □ According to homeopathic indications these ingredients temporarily relieve the symptoms of temperature above normal, discomfort, throbbing, and sleeplessness with earaches after diagnosis by a physician. Relieves common discomfort and itching of "swimmer's ear". *These statements are based upon traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

WARNINGS:

□USE ONLY AFTER DIAGNOSIS BY A PHYSICIAN AND UNDER THE SUPERVISION OF A PHYSICIAN.

□Keep away from the eyes.

- This product is intended to complement, not replace standard medical treatment. • Initial worsening of the symptoms may occur.
- A physician should always be consulted to rule out serious causes.
- **□If pregnant or breast-feeding, ask a health professional before use.**
- **Keep out of the reach of children.**
- If swallowed, get medical help or contact a Poison Control Center right away.

□Do not use

- If you have ear drainage, irritation, discharge or rash in the ear, consult a physician.
- With ear tubes, damaged ear drums or after surgery.
- If drops become cloudy.

□ Stop use and ask a doctor if

- Symptoms worsen or continue for more than 48 hours.
- There is discharge from the ear.
- A fever greater than 102°F is present.

OTHER SAFETY INFORMATION:

Active ingredients are micro-diluted in accordance with the Homeopathic Pharmacopoeia of the United States and are therefore non-toxic with no known side effects.

- Store at 15°C-30°C (59°F-86°F).
- Protect from light and excessive moisture.

†Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

DO NOT USE:

DO NOT USE IF INPRINTED SEAL ON CAP IS TORN, BROKEN OR MISSING.

KEEP OUT OF REACH OF CHILDREN:

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

Suitable for adults and children over the age of 2.

- For use in the ears only.
- Remove any hearing aids before using this product.
- Use 3 to 5 drops twice per day or as needed.
- Warm contents to body temperature by holding bottle in your hands.
- Tilt your head to the side and let solution drip into the ear. Never put the tip into the ear canal.
- Keep drops in your ear by tilting your head for 1-2 minutes or gently place cotton in the ear to keep drops in.

INDICATIONS:

•For use in the ears only. According to homeopathic indications these ingredients temporarily relieve the symptoms of temperature above normal, discomfort, throbbing, and sleeplessness with earaches after diagnosis by a physician. Relieves common discomfort and itching of "swimmer's ear". *These statements are based upon traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

INACTIVE INGREDIENTS:

benzalkonium chloride, citric acid, glycerin, purified water

QUESTIONS:

Distributed by: CVS Pharmacy, Inc.

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Woonsocket, RI 02895
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1-800-SHOP CVS
V-19655

PACKAGE LABEL DISPLAY:

CVS
Health
Compare to the
active ingredients in
Hyland's® Earache Drops
NDC 59779-568-15

Homeopathic

EarAche

EAR DROPS

- Relieves discomfort,
calms irritability*
- Soothes itching due to
cold, swimmer's ear
& allergy*

Package Contains

One Bottle

0.33 FL OZ (10mL)

NO PRINT AREA

Contents: Belladonna 30C HPUS, Calcarea Carbonica 30C HPUS, Chamomilla 30C HPUS, Lycopodium 30C HPUS, Pulsatilla 30C HPUS, Sulphur 30C HPUS

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

Directions: Suitable for adults and children over the age of 2. • For use in the ears only. • Remove any hearing aids before using this product. • Use 3 to 5 drops twice per day or as needed. • Warm contents to body temperature by holding bottle in your hands. • Tilt your head to the side and let solution drip into the ear. Never put the tip into the ear canal. • Keep drops in your ear by tilting your head for 1-2 minutes or gently place cotton in the ear to keep drops in.

Other information: Active ingredients are microdiluted in accordance with the Homeopathic Pharmacopoeia of the United States and are therefore non-toxic with no known side effects. • Store at 15°C-30°C (59°F-86°F). • Protect from light and excessive moisture.

Inactive ingredients: Benzalkonium Chloride, Citric Acid, Glycerin, Purified Water

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

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CVS Health. NDC 59779-568-15

Homeopathic EarAche™
EAR DROPS

- Relieves discomfort, calms irritability
- Soothes itching due to cold, swimmer's ear & allergy*

0.33 FL OZ (10mL)

CVS Quality
Money Back Guarantee

DO NOT USE IF IMPRINTED SEAL ON CAP IS
TORN, BROKEN OR MISSING.

INI 0313 R0216

Drug Facts

Active ingredients

Belladonna 30C HPUS.....Temperature above normal
Calcareo Carbonica 30C HPUS.....Burning ear
Chamomilla 30C HPUS.....Sleeplessness and irritability
Lycopodium 30C HPUS.....Ear discomfort
Pulsatilla 30C HPUS.....Ear itching, discomfort at night
Sulphur 30C HPUS.....Throbbing ear

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

Uses*

• For use in the ears only. According to homeopathic indications these ingredients temporarily relieve the symptoms of temperature above normal, discomfort, throbbing, and sleeplessness with earaches after diagnosis by a physician. Relieves common discomfort and itching of "swimmer's ear". *These statements are based upon traditional homeopathic practice. They have not been reviewed by the Food and Drug Administration.

Warnings

USE ONLY AFTER DIAGNOSIS BY A PHYSICIAN AND UNDER THE SUPERVISION OF A PHYSICIAN.

Keep away from eyes. • This product is intended to complement, not replace, standard medical treatment. • Initial worsening of symptoms may occur. • A physician should always be consulted to rule out serious causes. • **If pregnant or breast-feeding, ask a health professional before use.** • **Keep out of the reach of children.** • If swallowed, get medical help or contact a Poison Control Center right away.

Do not use • If you have ear drainage, irritation, discharge or rash in the ear, consult a physician • With ear tubes, damaged ear drums or after surgery. • If drops become cloudy.

Stop use and ask a doctor if

- Symptoms worsen or continue for more than 48 hours.
- There is discharge from the ear.
- A fever greater than 102°F is present.

Drug Facts (cont.)

Directions

Suitable for adults and children over the age of 2. • For use in the ears only. • Remove any hearing aids before using this product. • Use 3 to 5 drops twice per day or as needed. • Warm contents to body temperature by holding bottle in your hands. • Tilt your head to the side and let solution drip into the ear. Never put the tip into the ear canal. • Keep drops in your ear by tilting your head for 1-2 minutes or gently place cotton in the ear to keep drops in.

Other information

Active ingredients are micro-diluted in accordance with the Homeopathic Pharmacopoeia of the United States and are therefore non-toxic with no known side effects.

- Store at 15°C-30°C (59°F-86°F).
- Protect from light and excessive moisture.

Inactive ingredients

benzalkonium chloride, citric acid, glycerin, purified water

***Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.**

Compare to the active ingredients in Hyland's® Earache Drops™
NDC 59779-568-15

Homeopathic EarAche

EAR DROPS

- Relieves discomfort, calms irritability*
- Soothes itching due to cold, swimmer's ear & allergy*

Package Contains One Bottle

0.33 FL OZ (10 mL)

***Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.**

This product is not manufactured or distributed by Hyland's®, distributor of Earache Drops

DO NOT USE IF IMPRINTED SEAL ON CAP IS TORN, BROKEN OR MISSING

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FPO 80%
UPC# 050428386170
XXXXXX XXXXXX X

EARACHE

belladonna, calcarea carbonica, chamomilla, lycopodium clavatum, pulsatilla (vulgaris), sulphur liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-568
Route of Administration	AURICULAR (OTIC)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	30 [hp_C] in 1 mL
OYSTER SHELL CALCIUM CARBONATE, CRUDE (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	30 [hp_C] in 1 mL
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	30 [hp_C] in 1 mL
LYCOPodium CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPodium CLAVATUM SPORE - UNII:C88X29Y479)	LYCOPodium CLAVATUM SPORE	30 [hp_C] in 1 mL
PULSATILLA VULGARIS (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	PULSATILLA VULGARIS	30 [hp_C] in 1 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	30 [hp_C] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)				
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-568-15	10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	04/22/2016	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic			04/22/2016	

Labeler - CVS Pharmacy (062312574)

Registrant - Apotheca Company (844330915)

Establishment			
Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(59779-568) , api manufacture(59779-568) , label(59779-568) , pack(59779-568)