

EAR CARE EARACHE DROPS- atropa belladonna, anemone pulsatilla, lycopodium clavatum spore, matricaria chamomilla, and sulfur liquid

Rite Aid Corporation

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.

EAR CARE EARACHE DROPS

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Belladonna 30C HPUS	Fever
Calcarea Carbonica 30C HPUS	Throbbing ear pain
Chamomilla 30C HPUS	Sleeplessness and irritability
Lycopodium 30C HPUS	Ear pain
Pulsatilla 30C HPUS	Ear itching, pain worse at night
Sulphur 30C HPUS	Ear pain with burning

"HPUS" indicates the components of this product are officially monographed in the Homeopathic Pharmacopœia of the United States.

Uses*

• **For use in the ears only.** According to homeopathic indications these ingredients temporarily relieve the symptoms of fever, pain, throbbing, and sleeplessness with earaches after diagnosis by a physician. Relieves common pain and itching of "swimmers 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.

Stop and ask a doctor if:

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

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, with damaged ear drums or after surgery. if drops become cloudy.

Directions

Suitable for adults and children over the age of 2.

- For use in the ears only
- Remove any hearing aids
- Use 3-5 drops twice per day or as needed. Warm contents to body temperature by holding bottle in your hands. Tilt ear upward for at least 2 minutes after application or gently place cotton in ear to keep drops in. Tilt your head to the side and let solution drip into the ear. Never put the tip in 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.

Inactive ingredients

Benzalkonium Chloride, Citric Acid, Glycerine, Purified Water

Questions or comments?

(800) RITE-AID

(800-748-3243)

Other Information:

Active ingredients are microdiluted in accordance with the Homeopathic Pharmacopeia 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

PRINCIPAL DISPLAY PANEL - 10 mL Bottle Carton

NDC 11822-3644-3

ear care

earache drops

homeopathic

eases pain

calms and soothes

relieves itching due to

cold & flu, swimmers

ear & allergy

0.33 FL. OZ. (10 mL)



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-3644
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 CHAMOMILLA (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	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
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	30 [hp_C] in 1 mL

SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	30 [hp_C] in 1 mL
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Inactive Ingredients	
Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0K00R)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-3644-3	1 in 1 CARTON	08/03/2017	
1		10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		08/03/2017	

Labeler - Rite Aid Corporation (014578892)