

EARACHE REMEDY- ear drops liquid
Vitality Works, 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.

Earache Remedy

Earache Remedy

Aconitum napellus 6X

Belladonna 3X

Chamomilla 6X

Kali mur 3X

Plantago major 3X

Verbascum 6X

Earache Remedy

Grapefruit Seed Extract, Olive Leaf Extract, USP Purified Water

Earache Remedy

Keep this and all medicines out of reach of children. Before use with children under 3 years of age, or if you are pregnant or nursing seek the advice of your health care professional. Avoid contact with eyes. If symptoms persist for more than 4 days, or if there is discharge from the ear or perforation, discontinue use and contact your health care professional. In case of accidental overdose, seek professional assistance or contact a poison control center immediately. All the ingredients are edible but this is not intended for internal use.

Earache Remedy

Keep this and all medicines out of reach of children.

Earache Remedy

A homeopathic combination for the temporary relief of earaches, inflammation of the external and internal ear. For the temporary relief of earaches from congestion or swelling of middle ear or eustacian tubes.

Warm up bottle by gently rolling it between your hands before use. Tilt head sideways and place 2 to 3 drops into ear. Tip of applicator should not enter ear canal. Repeat 2-3

times/day for up to 4 days, if needed, or as directed by your health care professional.

Earache Remedy

Aconitum napellus - relieves earache, hot, painful, swollen ear.

Belladonna - relieves Otitis media, throbbing deep ear pain.

Chamomilla - relieves earache, soreness, swelling, otalgia.

Kali mur - relieves chronic catarrhal conditions of middle ear.

Plantago major - relieves earache, neuralgic earache, otalgia.

Verbascum - relieves catarrhs, otalgia with sense of obstruction.

Earache Remedy

SEAGATE EARACHE REMEDY Homeopathic NDC 064616-045-01

Do not use if the shrink seal marked "Sealed for your protection" is missing or has been tampered.

Active Ingredients: Aconitum napellus 6X, Belladonna 3X, Chamomilla 6X, Kali mur 3X, Plantago major 3X, Verbascum 6X

Indications: For the temporary relief of earaches; otitis media; inflammation of external and internal ear and eustachian tubes in adults and children 3 years of age and older.

Warnings: Keep out of reach of children. Avoid contact with eyes. If symptoms persist for more than 4 days, or if there is discharge from the ear or perforation, discontinue use and contact your health care professional. If you are pregnant or nursing, seek the advice of your health care professional. In case of accidental overdose, seek professional assistance or contact a poison control center immediately. All the ingredients are edible but this product is not intended for internal use.

Directions: Warm up bottle in your hand to body temperature before use. Tilt head sideways and place 2 to 3 drops into ear. Tip of applicator should not enter ear canal. Use up to 3 times/day for up to 4 days if needed, or as directed by a doctor. Before use with children under 3 years of age consult a doctor.

www.SeagateProducts.com 1-888-505-4283 Distributed by: First Fishery Development Services Inc. San Diego, CA 92123

For External Use net wt 0.5 fl. oz. (15 ml)

SEAGATE
ALL NATURAL HOMEOPATHIC
EARACHE REMEDY
SEAGATE NDC 064616-045-01
ALL NATURAL

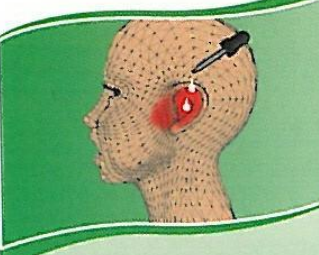
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or visit
www.SeagateProducts.com

Strong enough for adults, gentle enough for children.

Drug Facts	Purpose Relieves earache, hot, painful, swollen ear Relieves Otitis media, throbbing deep ear pain Relieves earache, soreness, swelling, otalgia Relieves chronic catarrhal conditions of middle ear Relieves earache, neuralgia, otalgia Relieves catarrhs, otalgia with sense of obstruction
Active Ingredients Aconitum napellus 6X Belladonna 3X Chamomilla 6X Xali mur 3X Plantago major 3X Verbascum 6X	Uses • A homeopathic combination for the temporary relief of earaches, inflammation of external and internal ear.
Other Information Store at room temperature out of direct sunlight. Does not require refrigeration	Directions • Warm up bottle by gently rolling it between your hands before use. • Tilt head sideways and place 2 to 3 drops in ear. Tip of applicator should not enter ear canal. • Repeat 2-3 times/day for up to 4 days, if needed or as directed by your health care professional
Warnings (Drug facts continued) • Keep this and all medicines out of reach of children. Before use with children under 3 years of age, or if you are pregnant or nursing, seek the advice of your health care professional. • Avoid contact with eyes. • If symptoms persist for more than 4 days, or if there is discharge from the ear or perforation, discontinue use and contact your health care professional. • In case of accidental overdose, seek professional assistance or contact a poison control center immediately. All the ingredients are edible but this not intended for internal use.	Inactive Ingredients Grapefruit Seed Extract, Olive Leaf Extract, USP Purified water

HOMEOPATHIC

EARACHE REMEDY



- Fast Pain Relief
- Soothing
- Reduces Swelling

SAFE FOR USE WITH OTHER Rx MEDICINE DOCTOR RECOMMENDED

For External Use **1/2 fl. oz. (15 ml)**

Homeopathy is a natural approach to medicine that works without contraindications (interference with other medications you may be taking) or side effects, to stimulate the body's curative responses so that the body heals itself.

Natural antimicrobial products derived from plant sources, are proving to be potent preventatives, treatments, and stimulants of the body's natural immune system, without the side-effects of many modern pharmaceutical drugs and are less susceptible to potency loss as a result of mutation by bacteria strains. The safe and effective relief of earache pain can be accomplished with natural ingredients.

Established in 1981, Seagate produces a variety of natural products from raw materials supplied by their fishing and organic farming operations:

- Colds and Flu Remedies
- Immune Support
- Joint Support
- Homeopathic Topical Skin Care
- Healthy Heart and Circulation
- Organic Fertilizer
- Organic Vegetable Concentrates

Call for a free catalog on all Seagate products 1-888-505-GATE or visit www.SeagateProducts.com

Distributed by:
First Fishery Development Services Inc.
San Diego, CA 92123



EARACHE REMEDY

ear drops liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64616-045
Route of Administration	AURICULAR (OTIC)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	6 [hp_X] in 1 mL
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	3 [hp_X] in 1 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	3 [hp_X] in 1 mL
PLANTAGO MAJOR (UNII: W2469WNO6U) (PLANTAGO MAJOR - UNII:W2469WNO6U)	PLANTAGO MAJOR	3 [hp_X] in 1 mL
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	6 [hp_X] in 1 mL
VERBASCUM THAPSUS (UNII: C9TD27U172) (VERBASCUM THAPSUS - UNII:C9TD27U172)	VERBASCUM THAPSUS	6 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)	
WATER (UNII: 059QF0KOOR)	
COBALT DISODIUM EDETATE (UNII: 3EY1Y2QRLI)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64616-045-02	1 in 1 CARTON	12/09/2005	
1	NDC:64616-045-01	15 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		08/23/2004	

Labeler - Vitality Works, Inc. (137752817)

Registrant - Vitality Works, Inc. (137752817)

Establishment

Name	Address	ID/FEI	Business Operations
Vitality Works, Inc.		137752817	manufacture(64616-045)