EARACHE RELIEF- belladonna, calcarea carbonica, chamomilla, hepar sulphuris calcareum, kali bichromicum, lycopodium clavatum, plantago major, pulsatilla (vulgaris) tablet

The Magni Company

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 12X, Calcarea Carbonica 12X, Chamomilla 12X, Hepar Sulphuris Calcareum 12X, Kali Bichromicum 12X, Lycopodium Clavatum 12X, Plantago Major 12X, Pulsatilla (Vulgaris) 12X.

USES:

For temporary relief of earache symptoms, such as pain, pressure, congestion, itching, sleeplessness, and headaches, after diagnosis by a physician.

WARNINGS:

- If pregnant or breastfeeding, ask a health professional before use.
- **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.
- **Stop use and ask a doctor if** you experience worsening symptoms or if symptoms last longer than 7 days.

KEEP OUT OF REACH OF CHILDREN:

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

OTHER INFORMATION:

- Store tightly closed in a cool, dry place (59° 86°F)
- Tamper sealed: Sealed for your protection. Do not use if seal is broken or missing
- The letters "HPUS" indicate that the components in this product are officially monographed in the Homeopathic Pharmacopeia of the United States
- These statements are supported by the traditional homeopathic principles

DIRECTIONS:

Adults and children 12 years and above: dissolve 1-2 tablets under tongue, 2 to 3 times daily or as directed by a physician.

Children under 12 years, consult a physician.

INDICATIONS:

For temporary relief of earache symptoms, such as pain, pressure, congestion, itching, sleeplessness, and headaches, after diagnosis by a physician.

INACTIVE INGREDIENTS:

Lactose, Magnesium Stearate, Microcrystalline Cellulose

QUESTIONS:

Dist. by: The Magni Group, Inc. McKinney, TX 75071 USA www.magnilife.com 1-800-645-9199

PACKAGE LABEL DISPLAY:

MAGNILIFE Homeopathic

NDC 43689-0020-1

EARACHE RELIEF

Targets ear pain for fast relief

Soothes ear pain and discomfort due to:

√ Allergy

√ Cold & Flu

√ Congestion

√Swimmer's Ear

90 Dissolving Tablets





EARACHE RELIEF

Product Type

belladonna, calcarea carbonica, chamomilla, hepar sulphuris calcareum, kali bichromicum, lycopodium clavatum, plantago major, pulsatilla (vulgaris) tablet

| Product Information | | |
|----------------------------|--|--|
| | | |

HUMAN OTC DRUG Item Code (Source)

NDC:43689-0020

| Active Ingredient/Active Moiety | | | | |
|--|---------------------------------------|-----------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII: WQZ3G9PF0H) | ATROPA BELLADONNA | 12 [hp_X] | | |
| OYSTER SHELL CALCIUM CARBONATE, CRUDE (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I) | OYSTER SHELL CALCIUM CARBONATE, CRUDE | 12 [hp_X] | | |
| MATRICARIA CHAMOMILLA WHOLE (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ) | MATRICARIA CHAMOMILLA WHOLE | 12 [hp_X] | | |
| CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q) | CALCIUM SULFIDE | 12 [hp_X] | | |
| POTASSIUM DICHROMATE (UNII: T4423S18FM) (DICHROMATE ION - UNII:9LKY4BFN2V) | POTASSIUM DICHROMATE | 12 [hp_X] | | |
| LYCOPODIUM CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479) | LYCOPODIUM CLAVATUM SPORE | 12 [hp_X] | | |
| PLANTAGO MAJOR WHOLE (UNII: W2469WNO6U) (PLANTAGO MAJOR - UNII: W2469WNO6U) | PLANTAGO MAJOR WHOLE | 12 [hp_X] | | |
| PULSATILLA VULGARIS WHOLE (UNII: 176KB35JEV) (ANEMONE PULSATILLA - UNII:176KB35JEV) | PULSATILLA VULGARIS WHOLE | 12 [hp_X] | | |

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| LACTOSE (UNII: J2B2A4N98G) | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | | |

| Product Characteristics | | | |
|-------------------------|----------------|--------------|----------|
| Color | white | Score | no score |
| Shape | ROUND (Convex) | Size | 6mm |
| Flavor | | Imprint Code | ML |
| Contains | | | |

| P | Packaging | | | |
|---|----------------------|---|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:43689- 0020-2 | 1 in 1 PACKAGE | 08/24/2016 | |
| 1 | NDC:43689- 0020-1 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|---------------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| unapproved homeopathic | | 05/09/2016 | |

Labeler - The Magni Company (113501902)

Registrant - Apotheca Company (844330915)

| Establishment | | | |
|---------------------|---------|-----------|--|
| Name | Address | ID/FEI | Business Operations |
| Apotheca Company | | 844330915 | manufacture(43689-0020) , api manufacture(43689-0020) , label(43689-0020) , pack(43689-0020) |

Revised: 1/2022 The Magni Company