

**DOLOEAR- apis melifica, aristolochia clematidis, belladonna, chamomilla, lachesis mutus, thuja occidentalis solution/ drops
Pharmadel LLC**

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.

DoloEar (Hcare)

Drug Facts

Active ingredients & Purposes

Active Ingredients** (HPUS)	Purposes*
Apis melifica 6C	Ear pain, inflammation
Aristolochia clematidis 6C.....	Ear inflammation
Belladonna 6C.....	Throbbing pain
Chamomilla vulgaris 6C	Ear pain irritability
Lachesis mutus 6C	Ear inflammation
Thuja occidentalis 6C	Earache from pressure

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

Uses*

Temporarily relieves earache symptoms associated with

- common pain and itching of swimmer's ear
- clogged ears
- ear pain or itching from other earaches after diagnosis by a doctor

Warnings

For use in ears only.

Do not use

if you have ear tubes, a damaged eardrum, or after surgery

Stop use and ask your doctor if

- symptoms persist for more than 48 hours or worsen
- symptoms are accompanied by a fever
- any discharge from the ear is present

If pregnant or breastfeeding,

seek professional advice before taking this product.

Keep out of the reach of children.

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

Directions

- shake before use

adults and children ages 6 and older:

- tilt head sideways and apply 2-3 drops into the ear (tip of dropper should not enter the ear canal)
- keep head tilted and allow drops to remain in the ear for 2 minutes or gently place cotton in ear to keep drops in
- repeat as needed, up to 4 times a day

children under 6 years of age: do not use

Other Information

- store in a cool dry place
- do not use if neckband seal is torn, broken, or missing

Inactive Ingredients

glycerin, water

Distributed by:

PHARMADEL LLC.
New Castle DE, 19720

+1-866-359-3478

Homeopathic Statements

*These "USES" claims have not been evaluated by the Food and Drug Administration (FDA). They are based on traditional homeopathic practices.

**C, K, CK and X are homeopathic dilutions.

PRINCIPAL DISPLAY PANEL

NDC 55758-327-15

DoloEar[®]

Earache Drops*

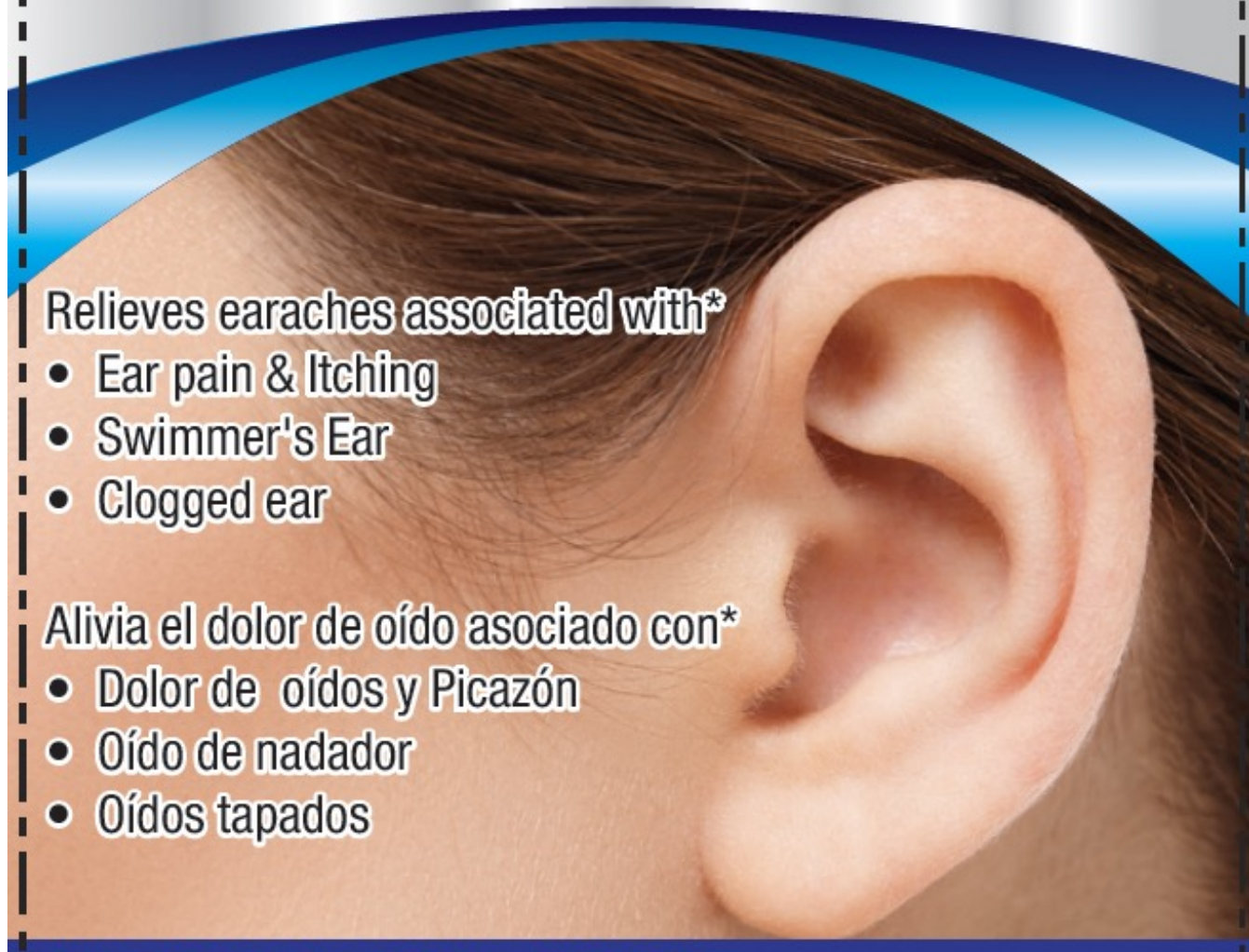
Gotas para el dolor de oído*

Relieves earaches associated with*

- Ear pain & Itching
- Swimmer's Ear
- Clogged ear

Alivia el dolor de oído asociado con*

- Dolor de oídos y Picazón
- Oído de nadador
- Oídos tapados



HOMEOPATHIC HOMEOPÁTICO

0.50 fl oz (15 mL)

DOLOEAR

apis mellifica, aristolochia clematidis, belladonna, chamomilla, lachesis mutus, thuja occidentalis
solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55758-327
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	6 [hp_C] in 15 mL
APIS MELLIFERA (UNII: 7S82P3R43Z) (APIS MELLIFERA - UNII:7S82P3R43Z)	APIS MELLIFERA	6 [hp_C] in 15 mL
ARISTOLOCHIA CLEMATITIS ROOT (UNII: ZY0NX0W00D) (ARISTOLOCHIA CLEMATITIS ROOT - UNII:ZY0NX0W00D)	ARISTOLOCHIA CLEMATITIS ROOT	6 [hp_C] in 15 mL
LACHESIS MUTA VENOM (UNII: VSW71SS07I) (LACHESIS MUTA VENOM - UNII:VSW71SS07I)	LACHESIS MUTA VENOM	6 [hp_C] in 15 mL
THUJA OCCIDENTALIS LEAFY TWIG (UNII: 1NT28V9397) (THUJA OCCIDENTALIS LEAFY TWIG - UNII:1NT28V9397)	THUJA OCCIDENTALIS LEAFY TWIG	6 [hp_C] in 15 mL
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	6 [hp_C] in 15 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-327-15	1 in 1 BOX	09/07/2023	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
unapproved homeopathic		05/23/2013	

Labeler - Pharmadel LLC (030129680)

Revised: 11/2023

Pharmadel LLC