DOLOEAR- atropa belladonna, apis mellifera, aristolochia clematitis root, matricaria recutita, lachesis muta venom, and thuja occidentalis leafy twig 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 (Homeocare)

Drug Facts

Active Ingredients HPUS:	Purpose
Belladonna 6C	Pain in ears, inflammation
Apis mellifica 6C	Pain in ears, inflammation
Aristolochia clematis 6C	Ear pain with tinnitus
Chamomilla 6C	Earache, toothache
Lachesis mutus 6C	Ear pain with wax build up
Thuja occidentalis 6C	Otalgia with noises in ears

Uses

For the temporary relief of earache associated with cold and flu, sore throat, swimmer's ear, sinusitis or wax build up.

Warnings

For use in ears only.

Do not use if you have: ear drainage, discharge, dizziness, ear tubes, damaged ear drum, or fever of 102 or greater.

Consult a physician before use: if pregnant or breastfeeding, in children under 2 years of age.

Stop use and ask your doctor: if symptoms worsen, reoccur, or persist for more than 48 hours, or if fever develops.

Keep out of the reach of children

Do not use if neckband is missing or broken

Directions

Adults and children: Remove tamper-evident neckband from bottle. Shake bottle before each use. Tilt head sideways and apply 2-3 drops into ear (to preserve purity, prevent tip of dropper from touching ear.) Allow drops to remain in ear by keeping head tilted or placing cotton in ear. Repeat as needed.

Inactive Ingredients

Glycerin USP, DI water.

Questions, Comments?

call 1-866-359-3478 M-F 9 AM to 5 PM Eastern Time

Distributed by: **PHARMADEL LLC.** ® Seaford, DE 19973

PRINCIPAL DISPLAY PANEL - 15mL Bottle Label

DoloEar™

Homeopathic Ear Drops

For the temporary relief of:
earache associated
with cold and flu,
sore throat,
swimmer's ear,
sinusitis or
wax build up.

0.50 FL OZ (15mL)



Drug Facts (continued)

Warnings (con't) Consult a physician before use: if pregnant or breastfeeding, in children under 2 years of age. Stop use and ask your doctor: if symptoms worsen, reoccur, or persist for more than 48 hours, or if fever develops Keep out of the reach of children Do not use if neckband is missing or broken

Directions Adults and children: Remove tamperevident neckband from bottle. Shake bottle before each use. Tilt head sideways and apply 2-3 drops into ear (to preserve purity, prevent tip of dropper from touching ear, Allow drops to remain in ear by keeping head tilled or placing cotton in ear. Repeat as needed.

Inactive Ingredients Glycerin USP, DI water.

Questions, Comments? call 1-866-359-3478 M-F 9 AM to 5 PM Eastern Time

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PHARMADEL LLC.*
Seaford, DE 19973
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DOLOEAR

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55758-001
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: ZYONXOWOOD) (ARISTOLOCHIA CLEMATITIS ROOT - UNII:ZYONXOWOOD)	ARISTOLOCHIA CLEMATITIS ROOT	6 [hp_C] in 15 mL
MATRICARIA RECUTITA (UNII: GOR4UBI2ZZ) (MATRICARIA RECUTITA - UNII:GOR4UBI2ZZ)	MATRICARIA RECUTITA	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 TWG	6 [hp_C] in 15 mL

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

I	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:55758- 001-15	15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	11/15/2019	

Marketing Information		
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	05/23/2013	
	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date

Labeler - Pharmadel LLC (030129680)

Revised: 12/2021 Pharmadel LLC