

ZONA DE TEXTO  
PLEGADO

**CLOTIC®**  
(clotrimazole)  
otic solution, 1%  
Rx only  
Rev. 10/2025

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**(clotrimazole)**  
**otic solution, 1%**  
Rx only  
Rev. 10/2025

30 mm  
30 mm

### 13 NONCLINICAL TOXICOLOGY

#### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

##### Carcinogenesis

No long-term studies of CLOTIC have been performed to evaluate carcinogenic potential. A 78-week oral (dietary) study of clotrimazole in rats did not show evidence of carcinogenicity at doses up to an equivalent of 150 mg/kg/day.

##### Mutagenesis

Clotrimazole has been studied in *in vitro* (bacterial) and *in vivo* (hamster spermatogonia) mutagenicity assays, and no evidence of mutagenic potential was found.

##### Impairment of Fertility

No reproduction toxicity studies were conducted with CLOTIC. Absorption of clotrimazole following topical administration is minimal.

### 14 CLINICAL STUDIES

#### 14.1 Osteoarthritis

The effectiveness and safety of CLOTIC were evaluated in two phase 3, multicenter, randomized, double-blind, placebo-controlled trials in adult patients with unilateral or bilateral otomycosis and intact tympanic membranes (Trial 1, NCT03686384; Trial 2, NCT03686397). The treatment regimen consisted of instilling the contents of one single-dose vial of CLOTIC or placebo in the affected ear canal(s) twice daily for 14 consecutive days. Trial 1 was performed in the U.S. and Mexico; Trial 2 was performed in Europe.

Out of 394 patients randomized in Trial 1 and Trial 2, 228 had a positive baseline fungal culture for *Aspergillus* species and/or *Candida* species (mycological intent-to-treat [MITT] population). These patients had a median age of 53 years (range 19 to 89 years); 54% were male, 86% were White, and 28% were Hispanic or Latino ethnicity.

Therapeutic cure was defined as both clinical cure and mycological cure at the test of cure visit which occurred on Day 24 to 26. Clinical cure was defined as a total signs/symptoms score of zero on a 4 point scale for pruritis, otalgia, ear fullness, and otorrhea. Mycological cure was defined as eradication (culture does not show growth of any fungal pathogen) or presumed eradication (there is no material to culture and the overall clinical outcome is clinical cure). In both trials, CLOTIC demonstrated superiority to placebo in the MITT population for the proportion of patients with therapeutic cure.

The results for therapeutic cure (both clinical cure and mycological cure) for each trial are presented in Table 2:

Table 2: Results of Therapeutic Cure in the MITT Population (Trials 1 and 2)

|                                    | Trial 1                   |                            | Trial 2                   |                            |
|------------------------------------|---------------------------|----------------------------|---------------------------|----------------------------|
|                                    | CLOTIC<br>N = 82<br>n (%) | Placebo<br>N = 36<br>n (%) | CLOTIC<br>N = 75<br>n (%) | Placebo<br>N = 35<br>n (%) |
| Therapeutic Cure                   | 48 (58.5)                 | 10 (27.8)                  | 59 (78.7)                 | 8 (22.9)                   |
| Treatment Difference<br>(95% CI) * | 30.8 (12.7, 48.9)         |                            | 55.8 (39.1, 72.5)         |                            |
| p-value                            | 0.0021                    |                            | < 0.0001                  |                            |

\*95% confidence interval for between-treatment group difference is based on Wald method

### 16 HOW SUPPLIED/STORAGE AND HANDLING

#### How supplied

CLOTIC is a sterile otic solution of clotrimazole 1% packaged in low-density polyethylene (LDPE) single-dose vials with a deliverable volume of approximately 0.17 mL. The solution is clear colorless to slightly yellow. The vials are contained in an aluminum foil overwrap pouch and a carton box for protection from moisture. Each carton box contains 2 foil pouches. Each pouch contains two strips of 7 single-dose vials. There are a total of 28 vials (NDC 15370-220-28).

#### Storage and Handling

Store at 20°C to 25°C (68°F to 77°F). Brief exposure to 15°C to 30°C (59°F to 86°F) permitted (see USP Controlled Room Temperature). Store unused vials in the foil pouch to protect from humidity. Do not open foil pouch until ready to use. Discard vial after use. Discard unused vials 30 days after first opening the pouch.

### 17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

#### Administration Instructions

- Advise patients that CLOTIC is for otic use only.
- Advise patients to warm the otic solution by holding the vial in the hand for 1 to 2 minutes before instilling it in the ear, to avoid dizziness [see Dosage and Administration (2.2)].

CLOTIC is:

Manufactured by:  
PHARMALoop, S.L.  
Pol. Industrial Azque – c/ Bolivia,15  
Alcalá de Henares, 28806 MADRID

Distributed by:  
Carwin Pharmaceutical Associates, LLC  
1301 Hwy 36 - Suite 11  
Hazlet, NJ 07730 USA

Under license of Laboratorios Salvat, S.A.

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### INSTRUCTIONS FOR USE CLOTIC ['klɒtɪk] (clotrimazole) otic solution

This Instructions for Use contains information on how to use CLOTIC.

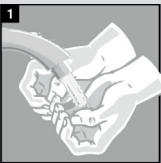
#### Important Information You Need to Know Before Using CLOTIC:

- For otic use only** (use in the ear).
- Use CLOTIC exactly as your healthcare provider tells you to use it.
- Apply the entire dose of CLOTIC from 1 single-dose vial, into the affected ear 2 times a day (for a total of 2 single-dose vials a day) for 14 days. Each dose should be about 12 hours apart.
- Do not use CLOTIC after the expiration date (EXP) appearing on the outer carton, pouch and single-dose container. The expiration date is the last day of that month, for example, 2025-DEC means the medicine expires December 31, 2025.

#### Using CLOTIC

Follow these instructions (**Step 1 to Step 11**) each time you use CLOTIC. Ask your healthcare provider if there is anything you do not understand.

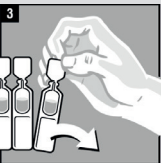
- Step 1.** Wash your hands with soap and water (Figure 1).



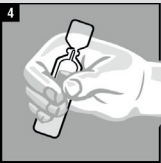
- Step 2.** Gently clean any fluid (discharge) from the outer ear using a clean cloth or tissue (Figure 2). Do not put a cotton swab or any other object in the ear canal.



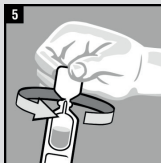
- Step 3.** Remove CLOTIC from the protective foil pouch. Pull apart 1 single-dose vial of CLOTIC as shown, by tearing along the dotted lines (perforations) until it is fully separated (Figure 3). Place the unused vials back into the protective foil pouch



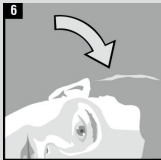
- Step 4.** Warm the dose of CLOTIC by holding the vial in your hand for 1 to 2 minutes (Figure 4).



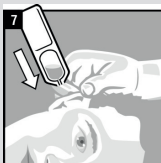
- Step 5.** Twist off the vial cap in the direction of the arrow as shown in Figure 5.



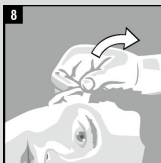
- Step 6.** The person receiving CLOTIC should be on his or her side with the affected ear up as shown in Figure 6.



- Step 7.** Hold the vial of CLOTIC in your hand and place the vial close to the ear. Let the entire dose of CLOTIC fall into the affected ear (Figure 7).



- Step 8.** Gently pull the outer ear lobe upward and outward (Figure 8). This will allow the ear drops to flow down into the ear canal.



- Step 9.** Remain on your side with the affected ear facing upward for 1 minute (Figure 9).



- Step 10.** If your healthcare provider has told you to use CLOTIC in both ears, repeat Steps 2 to 9 in the other ear.

- Step 11.** Safely throw away CLOTIC vials after use.

#### How should I store CLOTIC?

- Store the carton at room temperature between 68°F to 77°F (20°C to 25°C).
- Do not open the foil pouch until ready to use.
- Keep unused vials in the foil pouch to protect from humidity.
- Throw away unused vials 30 days after first opening the pouch.
- When a vial is opened, use it right away and throw away (discard) the vial after use.

#### Keep CLOTIC and all medicines out of the reach of children.

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This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Approved: October 2025

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#### Keep CLOTIC and all medicines out of the reach of children.

#### General information about the safe and effective use of CLOTIC.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use CLOTIC for a condition for which it was not prescribed. Do not give CLOTIC to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about CLOTIC that is written for health professionals.

#### What are the ingredients in CLOTIC?

**Active ingredient:** clotrimazole

**Inactive ingredient:** polyethylene glycol 400 (PEG 400)

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For more information, go to [www.carwinpharma.com](http://www.carwinpharma.com) or call 1-844-700-5011.

This Patient Information has been approved by the U.S. Food and Drug Administration

Issued: 10/2025

360 mm

10

10

420 mm