

**PACKAGE LEAFLET: INFORMATION FOR THE USER****Infester<sup>®</sup>**

28% w/w nail lacquer, Tioconazole

**1. IDENTIFICATION OF THE PHARMACEUTICAL PRODUCT****1.1. Trade Name****Infester<sup>®</sup>****1.2. Composition**

Active substance: Tioconazole.

Excipients: Undecylenic acid, Ethyl acetate.

**1.3. Pharmaceutical form**

Nail lacquer.

**1.4. Quantitative composition**

Each g of the nail lacquer solution contains 280 mg Tioconazole.

**1.5. Nature and content of the container****Infester<sup>®</sup>** nail lacquer is packed a glass vial with a screw-on safety cap with applicator. Each vial contains 12 of solution.**1.6. Pharmacotherapeutic category**

Imidazole and triazoles derivatives.

**1.7. Manufacturer**

A) RAFARM AEBE, 12 Korinthou st., N. Psychico, 154 51, Athens Greece.

B) HELP ABEE, 4 Valaoritou st., Metamorphosis, 144 52, Athens Greece.

**1.8. Marketing Authorization Holder**

TARGET PHARMA LTD., 54 Menandrou st., 104 31 Athens Greece,

Tel.: +30 210 5224830, Fax: +30 210 5224838, E-mail: [info@targetpharma.gr](mailto:info@targetpharma.gr),[www.targetpharma.gr](http://www.targetpharma.gr)**2. WHAT SHOULD THE PATIENT KNOW ABOUT THIS MEDICINE**

**Information on this leaflet only refers to the specific medicine that your doctor has recommended for you. Please read the instructions carefully. In this leaflet are included important information, but not everything is included. If you have additional questions or if you are not sure, ask your doctor or pharmacist.**

**2.1. Indications**Tioconazole is an anti-fungal imidazole agent with a wide-range of action. **Infester<sup>®</sup>** nail lacquer is

indicated for the topical treatment of nail infections due to sensitive fungi (dermatophytes and yeasts).

## 2.2. Contraindications

**Infester**<sup>®</sup> is contraindicated to patients that have hypersensitivity to imidazole anti-fungal agents or to any of the excipients of the medicine.

The use of this medicine is not indicated during pregnancy.

## 2.3. Special warnings and precautions for use

### 2.3.1. General

**Infester**<sup>®</sup> is not intended for ocular use.

### 2.3.2. Pregnancy and Lactation

*Use during pregnancy:* Animal studies have shown that Tioconazole does not have terotogenic effect. When administered at high doses, it increased the incidence of kidney abnormalities in rat embryos, but this effect was small and transient and was not apparent in weaned animals. There is insufficient data on the safety of the drug during pregnancy, although absorption after topical administration is negligible. However, the use of **Infester**<sup>®</sup> is contraindicated during pregnancy due to prolonged treatment time for nail infections. If pregnancy is confirmed, administration should be discontinued.

*Use during lactation:* It is not known if the medicine is excreted to human breast milk. As many drugs are excreted in breast-milk, lactation should be temporarily discontinued during the administration of **Infester**<sup>®</sup>.

### 2.3.3. Effect on the ability to drive or use machinery μηχανημάτων

None known.

## 2.4. Interactions with other medicines or substances

None known.

## 2.5. Posology and instructions of use

Route of administration: topical.

**Infester**<sup>®</sup> nail lacquer is intended to topical use.

### Adults:

Nail lacquer should be applied to infected nails and immediate skin environment, every twelve hours, using the applicator. Once a week or more frequently the nail plate should be filed.

The duration of the treatment reaches six month. However treatment duration may be extended up to twelve months.

### Use in elderly:

No special precautions are required. The same dose as for adults may be applied.

### Use in children:

No special precautions are required. The same dose as for adults may be applied.

## 2.6. Overdose - Management

No cases of overdose with **Infester**<sup>®</sup> have been reported. In case of accidental excessive ingestion, gastrointestinal problems may occur. In such cases, appropriate measures should be taken to empty the stomach content.

## 2.7. Possible side effects

**Infester**<sup>®</sup> is usually well tolerated when applied locally. There are reports of symptoms like local irritation during the first week of treatment, but such symptoms are usually mild and transient. However, if a sensitivity reaction occurs with **Infester**<sup>®</sup>, the administration should be discontinued and appropriate treatment applied.

*Skin and subcutaneous tissue disorders (at the site of application):* bullous rash, dermatitis, itching, pain, edema, burning sensation, contact dermatitis, dryness, nail disorders (nail discoloration, pricks inflammation and nail pain), rash, skin exfoliation, skin irritation.

*Immune system disorders:* allergic reaction (including peripheral edema, periorbital edema and urticaria).

If you get any side effects, please talk to your doctor or pharmacist or any other health care provider or directly to the National Medicines Agency (284 Mesogion Av., 15562, Chologos, Athens, Greece [www.eof.gr](http://www.eof.gr)).

## 2.8. What you should know in case you forgot to take one dose

If you forget one or more doses, you should talk to your doctor or pharmacist. It is important to follow the instructions of use exactly as your doctor prescribed.

## 2.9. What should the patient know about the expiration date

It is written in outer and inner packaging.  
Do not use this medicine if this date has expired.

## 2.10. Special warnings about the storage of the product

Store this product in temperature less than 25°C. Do not freeze.

## 2.11. Date of last revision of this leaflet

28 January 2015

## 3. INFORMATION FOR THE RATIONAL USE OF MEDICINES

- This pharmaceutical product was prescribed by your doctor to you, according to your medical history and condition. Do not pass the product to others or use it in any other condition even if the symptoms may appear the same and without receiving your doctor's or pharmacist's advice.
- If during treatment with this medicine you experience any problem or issue, contact immediately your doctor or pharmacist.
- If you have any questions regarding the information for this product, its use or about the medical condition that you suffer, you should ask your doctor or pharmacist.
- This product will be safe and effective if it is used exactly according to instructions provided.
- For your own safety it is highly recommended that you read carefully all information provided for the prescribed medicine.

- Do not store medicines in bathroom lockers, as the high temperature and the humidity may degrade the product which may be harmful to your health.
- Store the product in the original packaging.
- If your doctor instructed you to stop the use of this product, dispose the remaining product and do not use it.
- Do not keep the medicine you do not need any more or those that are expired.
- Keep all medicines in safe place out of reach and sight of children.

#### **4. PRESCRIBING INFORMATION**

This product is not subjected to a medicinal prescription.

Tel of Poison Center Athens: +30 210 779377

