

**Package leaflet: Information for the patient**

**Onytec 80 mg/g medicated nail lacquer**

For adults

ciclopirox

[For medicines available only on prescription]

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

1. What Onytec is and what it is used for
2. What you need to know before you use Onytec
3. How to use Onytec
4. Possible side effects
5. How to store
6. Contents of the pack and other information

**1. What ONYTEC is and what it is used for**

Onytec contains the active substance ciclopirox, which belongs to a group of medicines known as antifungals. It kills a wide range of fungi that can cause nail infections.

Onytec is used to treat mild to moderate fungal infections of the nails without nail matrix/lunula (white half-moon of the nail) involvement in adults.

**2. What you need to know before you use ONYTEC**

- Mild to moderate nail fungal infection affects up to 75% of the nail surface, involving a maximum of 5 nails in total (including toenails and/or fingernails), without involving nail matrix (lunula).

**Do not use Onytec:**

- if you are allergic to ciclopirox or any of the other ingredients of this medicine (listed in section 6)
- in children and adolescents below 18 years of age due to insufficient experience in this age group

## **Warnings and precautions**

### **Talk to your doctor or pharmacist before using Onytec**

- In case of involvement of more than 75% of nail surface, or of multiple nails (> 5 nails), or of nail matrix (lunula)
- If you become sensitive to the product, please stop treatment and consult a doctor.
- If you have a history of diabetes, immune disorders, peripheral vascular disease, injury, painful or seriously damaged nails, skin conditions such as psoriasis or any other chronic skin condition, oedema, breathing disorders (Yellow nail syndrome).
- If you are a diabetic patient, please take care when trimming the nails.
- Avoid contact with the eyes and mucous membranes (e.g. mouth and nostrils).
- Onytec is for external use only.
- Do not use nail polish or other nail cosmetic products on the treated nails.
- Keep the bottle capped when not in use

### **Children and adolescents**

Onytec is contraindicated in children and adolescents below 18 years of age (see section 2 "Do not use Onytec")

### **Other medicines and Onytec**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

### **Pregnancy and breast-feeding**

#### Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby ask your doctor or pharmacist for advice before taking this medicine.

Treatment with Onytec should only take place after consulting a doctor.

#### Breast-feeding

It is not known whether ciclopirox passes into breast milk of humans. Treatment with Onytec should only take place, if treatment is urgently required, after consulting a doctor.

### **Driving and using machines:**

Onytec has no influence on the ability to drive and use machines.

### **Onytec contains alcohol (ethanol)**

This medicine contains 730 mg alcohol (ethanol) in each gram of solution. It may cause a burning sensation on damaged skin.

This product is flammable. Keep away from heat and open flame.

### **Onytec contains cetostearyl alcohol**

This may cause local skin reactions (e.g. contact dermatitis).

### **3. How to use ONYTEC**

[For medicines available only on prescription]

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Method of administration:

Cutaneous use (Only for use on nails and immediately adjacent skin).

Onytec is for use in adults only.

The recommended dose is to apply in a thin layer once a day on infected nail/s. For this, the nails should be carefully washed and dry. The medicated nail lacquer shall be applied over the entire nail surface and 5 mm of surrounding skin. If possible, Onytec should be applied also under the free edge of the nail.

Allow Onytec to dry for approximately 30 seconds.

The nail(s) should not be washed for at least 6 hours, therefore, application in the evening before going to bed is recommended. After that time, normal hygienic practices can be followed.

Onytec does not need to be removed by any solvent or abrasives (i.e. nail filing), it is sufficient to wash the nails with water. In case of unintentional removal by washing, Onytec can be applied again. Regular removal of unattached parts of the infected nail, e.g. by clipping the nails, is recommended.

Treatment should be continued until the problem has disappeared, that means till the nail(s) is/are clear or their appearance is significantly improved and healthy nail/s has/have grown again. Normally, treatment duration of fingernails is for about 6 months while for toenails it is about 9 to 12 months.

#### **If you use more Onytec than you should:**

In case of accidental ingestion of the bottle content or part of it, go immediately to the nearest hospital or poisoning centre. Bring the package with you.

#### **If you forget to use Onytec:**

If you forget to apply the product once, do not use a double dose to make up for it. Continue with treatment as recommended by your doctor or as explained at point 3 of this leaflet (How to use Onytec). In case you did not use the medicated nail lacquer for several days, the efficacy may be reduced.

#### **If you stop using Onytec:**

If you stop treatment with Onytec before your nail/s is/are clear or their appearance is significantly improved and healthy nail/s has/have grown again, the fungi may not have disappeared. In this case, the condition of your nails can get worse again.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very rare side effects: may affect up to 1 in 10,000 people

- application site redness, scales, burning and itching.

Not known (frequency cannot be estimated from the available data):

- Rash, eczema; allergic dermatitis, also beyond the application site.
- (Transient) nail discoloration (this reaction can also be attributed to the fungal nail disease itself).

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via [www.hpra.ie](http://www.hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store ONYTEC**

Keep this medicine out of sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton box and on the bottle.

The expiry date refers to the last day of that month.

Keep the bottle in the outer carton, in order to protect from light.

Do not refrigerate or freeze.

This product is flammable. Keep away from heat and open flame.

After first opening the container:

Keep the bottle tightly closed to avoid evaporation of the content.

After first opening use within 6 months.

At temperature below 15°C the medicated nail lacquer may gel. Light flocculation or formation of a light sediment may also occur which can be reversed by warming up to room temperature (25°C) through rubbing the bottle between hands till the solution is clear again (about one minute). This has no impact on product quality or performance.

Do not throw away any medicines via wastewater <or household waste>. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Onytec contains:**

The active substance is ciclopirox. One gram of medicated nail lacquer contains 80 mg of ciclopirox.

The other ingredients are: ethyl acetate, ethanol (96%), cetostearyl alcohol, hydroxypropyl-chitosan and purified water.

### **What Onytec looks like and contents of the pack:**

Medicated nail lacquer

Onytec is a clear, colourless to slightly yellowish solution supplied in clear glass bottles with screw caps which are fitted with a brush.

Pack sizes are 3.3 ml and 6.6 ml.

Not all pack sizes may be marketed

### **Marketing Authorisation Holder**

Polichem S.A.

50, Val Fleuri

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Luxembourg

### **Manufacturer**

Almirall Hermal GmbH

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Italy

**This medicine is authorised in the Member States of the European Economic Area under the following names:**

BE Myconail 80 mg/g vernis à ongles médicamenteux

CY Kitonail 80 mg/g medicated nail lacquer

DE Decme 80 mg/g wirkstoffhaltiger Nagellack

DK Onytec

ES Kitonail 80 mg/g Barniz de uñas medicamentoso

FI Onytec 80 mg/g Lääkekynsilakka

FR Myconail 80 mg/g Vernis à ongles médicamenteux

IE Onytec 80 mg/g medicated nail lacquer

LT Onytec 80 mg/g ārstnieciskā nagu laka

LV Onytec 80 mg/g ārstnieciskā nagu laka

NO Onytec

SE Onytec 80 mg/g Medicinskt nagellack

SI Onytec 80 mg/g zdravilni lak za nohte

**This leaflet was last revised in {MM/YYYY}.**