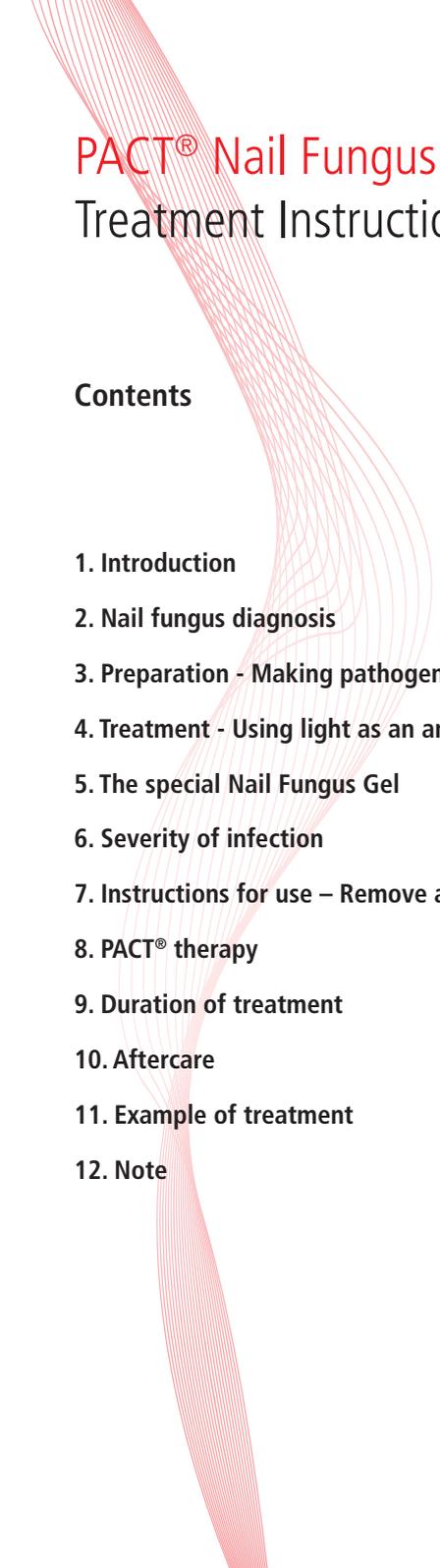




PACT®

PACT® Nail Fungus Therapy Treatment Instructions

Photodynamic therapy
for nail fungus –
using light, safely and gently.



PACT® Nail Fungus Therapy

Treatment Instructions

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1. Introduction

PACT® is an abbreviation and a scientific term that stands for Photodynamic Antimicrobial Therapy. With this method, fungus can be killed effectively on both toenails and fingernails.

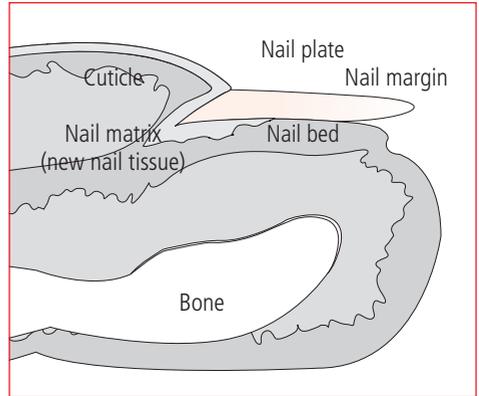


Diagram of a toe with nail anatomy.

2. Nail fungus diagnosis

The characteristic signs and symptoms of nail fungus infection are usually sufficient for a visual diagnosis to be performed by a specialist. If it is unclear, scrapings can be taken from the infected nail and examined directly under a microscope for the diagnosis to be confirmed. A culture is required to determine the precise species of fungus. Not every nail change is a case of onychomycosis.

There are numerous causes, e.g. psoriasis or infections that may have similar pathological forms. If findings are indistinct, a doctor should be consulted.



3. Preparation

Making pathogens sensitive to light

As opposed to human cells, fungi possess a cell wall. This cell wall can be stained with a dye that is harmless to human cells but that stain selectively makes fungi sensitive to a specific wavelength of light.

4. Treatment

Using light as an antimycotic

By conducting light treatment with a PACT® high-power LED lamp the stained cell wall of the fungus is attacked and destroyed. The fungus can no longer continue to grow. Repeating the treatment ensures that the fungus is destroyed even if infection is severe and penetrates deeply within the nail as deeply in the tissues as is necessary.

5. The special Nail Fungus Gel

The PACT® Nail Fungus Gel was specially developed for application to toenails and fingernails and it only works in combination with exposure to light from a PACT® MED light device.



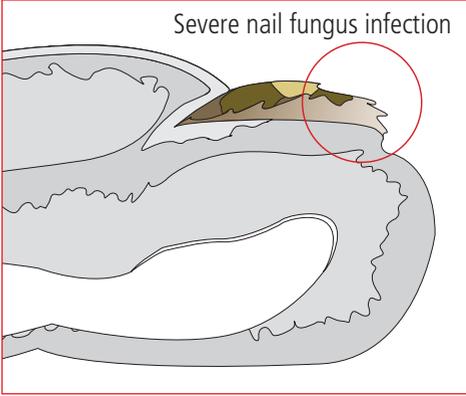
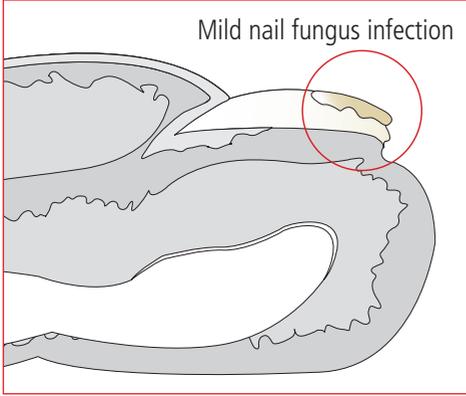
6. Severity of infection

The following distinctions are made:

	A) Toenail fungus - mild infection	B) Toenail fungus - severe infection	C) Fingernail fungus
Type of patient	Usually 30–60 years of age, mild infection.	Podiatry patients with concomitant disorders and severe infection.	All those affected
PACT® therapy	Nail burring, PACT® treatment 3-x 10 minutes within a 7 day period (1x 10 minutes after one month if necessary), finished. The nail grows out.	Depending on the disorder, age and nail growth, PACT® initial treatment (3-x 10 minutes within a 7 day period) must be accompanied by 10-minute sessions of irradiation once a month over a lengthy period, as necessary.	Nail burring, daily over a lengthy period, 10-minute sessions of light treatment.
Follow-up treatment	Possible at any time if the fungus fails to grow out completely or if repeat infection occurs.	This can be conducted for up to 6 months or longer.	3–6 months, depending on severity of infection

In all cases, PACT® therapy must be preceded by the removal of ample nail tissue, which can be performed mechanically with a burr or with a combination of urea plaster and scissors/burr.

No matter whether the infection is mild, medium or severe, therapy must always be preceded by removal of the infected nail tissue.



An infected nail (onychomycosis)
 The nail fungus usually grows from the tip of the nail to the nail bed.

A severely infected nail
 If infection is severe, the nail matrix is also affected.



Mild infection



Medium infection



Severe infection

7. Instructions or use – Remove all infected nail tissue

If a large area is infected, the surface of the nail is reduced in thickness - do not remove the entire nail!

As soon as 50% of the nail tissue infected with fungus has grown out, burring should be performed again and treatment should be repeated 3 times.

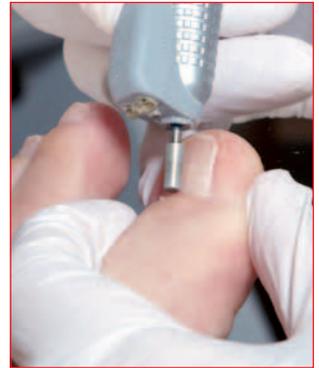
If the matrix (nail root) is also infected: burring of the nail must initially be performed and access

under the nail fold must be carefully be created.

The patient should then be treated at home with a 40% urea plaster for several days (follow the instructions provided by the manufacturer of the urea plaster) before PACT® treatment can be conducted.



Mechanical removal of all the infected nail tissue.



If infection is severe, thin out the surface of the nail.

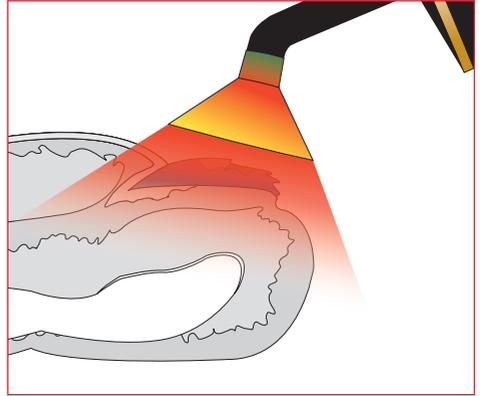
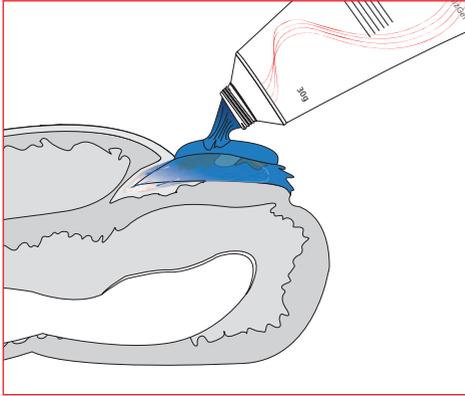


Then apply a nail plaster with urea ointment.

8. PACT® therapy

The prepared nail can now be generously coated with PACT® Nail Fungus Gel and left for at least 10 minutes before being subjected to light

treatment with the PACT® lamp for 9.5 minutes. It is best to position the silicone anti-glare shield about 1 mm above the edge of the nail.



Each infected nail must be subjected to light treatment separately but the gel can be applied simultaneously.



It is best to use the supplied small stand, whereby the foot to be treated is placed flat on the floor.

9. Duration of treatment

Treatment must always be performed at least 3 times within a week and then repeated once after a month.

If infection is severe, if the matrix is involved or if conditions are unfavourable (e.g. sauna worker), treatment should be performed at regular

intervals, e.g. every six months.

In doing so the nail surface only has to be roughened slightly and the removal of nail tissue is only necessary if fungal infection is visible.

10. Aftercare

To prevent re-infection, clothing such as socks should be subjected to antimicrobial treatment and always washed at a temperature of 60°C.

Before footwear is worn, it should always be treated with an anti-fungal spray, over a period of at least 4 weeks.

11. Example of treatment

Male patient, 47 years of age

Findings: severe nail mycosis

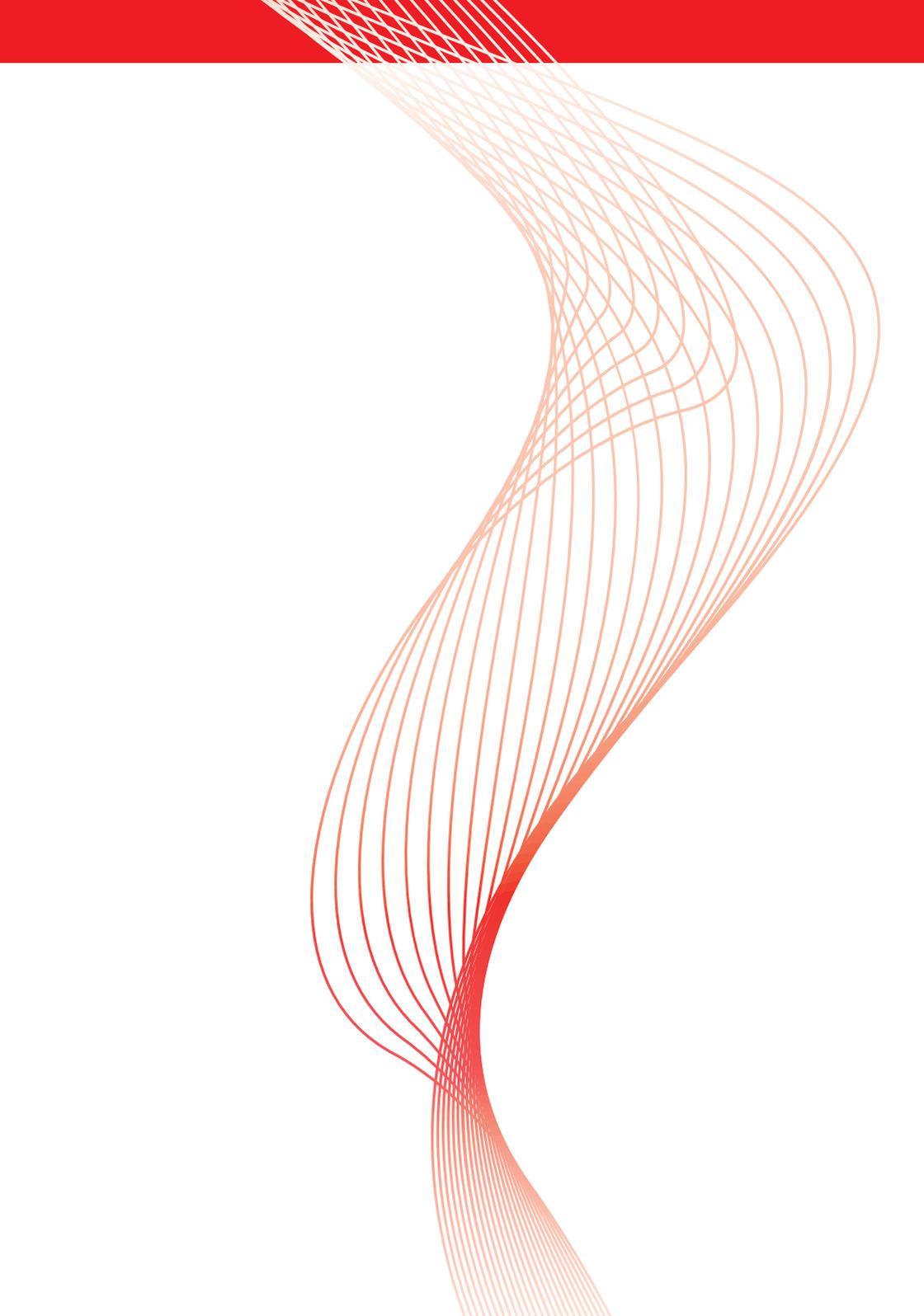
Initial laboratory diagnosis: Trichophyton rubrum, laboratory findings after three sessions of treatment. Devoid of fungus. Second picture 3 months after the first treatment.

(Documentation: Eef Ankersmit, Amsterdam)



12. Note

Please observe the user information concerning the PACT® MED LED lamp and the PACT® Nail Fungus Gel.



If you have any questions, please contact:



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