

Treatment Instructions

Nail Fungus



PACT[®]

Hahn Medical Systems

Introduction

Nail fungus is curable! With a tailored combination of UREA ointment and PACT® (photo-activated) therapy. The treatment can also be combined with medically prescribed oral therapy.

These Treatment Instructions are based on the clinical experience and podiatric practice of many hundreds of practitioners. In contrast to the use of varnishes or oral therapy, PACT® treatment can and should be individually matched to the nail treated.

Nail fungus diagnosis:

There are characteristic signs and symptoms of nail fungus infection, so a visual diagnosis is usually sufficient. If in doubt, the patient may be referred to a specialist or they can commission a laboratory by submitting a nail scraping sample as a self-paying patient (cost approx. 40,- € per sample). The relevant forms for Germany and sterile sample tubes are available from **www.hahnmedicalsyste.ms.com**.

You can take the nail sample yourself or it can be taken by a specialist (e.g. podiatrist / pedicurist), preferably in the region between the infected and healthy nail material.

Nail fungus / Stages of the disease

In case of nail fungus diseases, mild, medium and severe infections are distinguished. In order to achieve the optimum treatment outcome, PACT® Nail Fungus Therapy has to be matched to the degree of the disease.

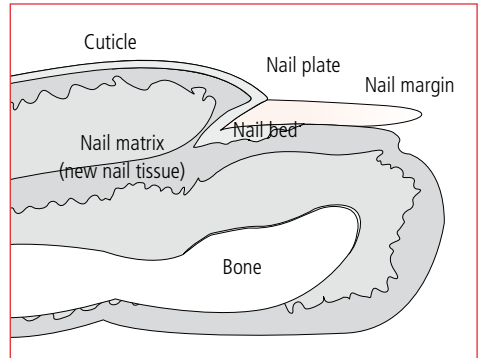


Diagram of a toe with nail anatomy.



Mild infection:

Max. $\frac{1}{4}$ of the nail plate is infected, not more than half way towards the proximal (to the body) nail fold.



Medium infection:

Max. $\frac{2}{3}$ of the nail plate is infected, up to a quarter of the way to the proximal nail fold; a mild infection is also treated as a medium infection if more than three toes are infected.



Severe infection:

More than $\frac{2}{3}$ of the nail plate, longitudinal infection up to the nail fold, hyperkeratosis (thickening of the nail).

Categorisation of the severity of nail fungus infection is based on the classification from Carney et al. published in JAMA Dermatology 2011: Onychomycosis Severity Index (Arch Dermatol. 2011 Nov;147(11):1277-82; Freely available from "The JAMA Network"; www.jamanetwork.com).

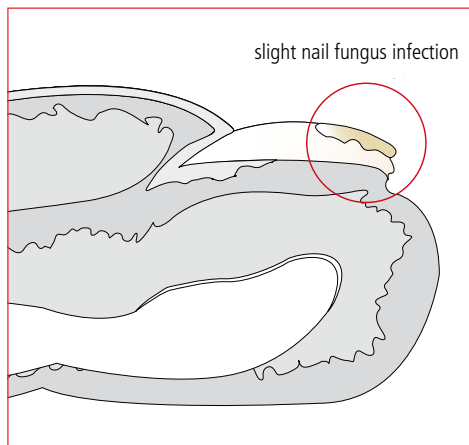
Mild infection

Treatment of mild infection:

Treatment with PACT® UREA 40 may be sufficient for mild infection. PACT® UREA 40 contains urea (approx. 40%). PACT® UREA 40 can dissolve the brittle (or fungal infected) part of the nail.

The damaged part of the nail can be detached and cautiously cut off or removed with a nail file.

- Thoroughly roughen the affected nail with the nail file where there is damage or places infected with fungus. Remove the nail material with the help of nail scissors.
- Now apply the ointment generously once a day, preferably after showering, on the affected nail such that the entire nail surface, including the healthy surface, is covered. Cover the nail treated this way with a plaster (dressing) for 24 hours. Tear off the required quantity of plaster tape, use two plasters if necessary.



Max. $\frac{1}{4}$ of the nail plate is infected, not more than half way towards the proximal (to the body) nail fold.

- Repeat the treatment with the ointment every day, remove the excess ointment of the last application. Use the nail file provided or nail scissors to detach the damaged part of the nail. Depending on the scale of damage (fungus infection) and the thickness of the nail, this treatment takes 2 to 3 weeks.
- After this 2–3 week treatment, the damaged part of the nail should be detached, the softened nail material can now be removed by a specialist (pedicurist or podiatrist).
- The nail is now soft and supple and can regrow healthily. The PACT® UREA 40 ointment should now be applied daily without a plaster to keep the nail soft until it is fully regrown (duration: 3–6 months).
Combining with a PACT® treatment (see pg. 8 f) can enhance or accelerate the success of therapy.

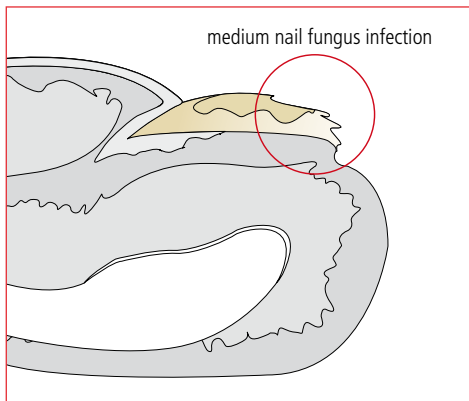


Treatment of medium infection:

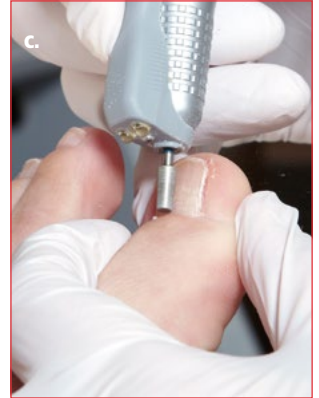
Firstly the modified nail material is burred off by the podiatrist and removed using PACT® UREA 40 ointment over two weeks as described above. In the case of infection over a large area, the nail is thinned out over the full area - do not remove the entire nail! As soon as the nail material affected by fungus has grown out by 50 %, burring should be performed again and the treatment repeated. PACT® UREA 40 must then be applied daily with a plaster for at least a week.



Medium infection



Max. $\frac{2}{3}$ of the nail plate is infected, up to a quarter of the way to the proximal nail fold; mild infection is also considered to be medium infection if more than three toes are affected.



Mechanical removal of all infected nail material **(a. + b.)**.

In case of severe infection - thin out the nail surface **(c.)**.

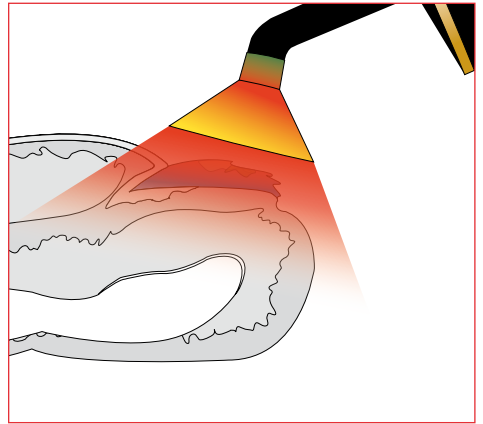
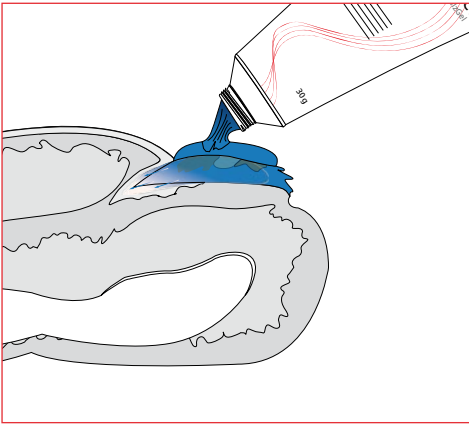
Thereafter - nail plaster with PACT® UREA 40 ointment **(d. + e.)**.

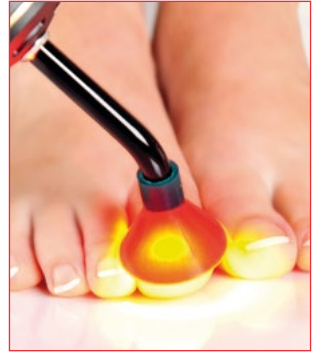
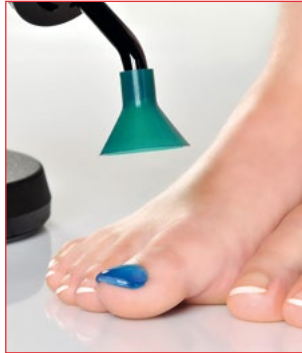
PACT® Therapy

The prepared nail is now generously covered with PACT® Nail Fungus Gel and after leaving for at least 10 minutes is illuminated with the PACT® Phototherapy Lamp for 9.5 minutes. It is best to position the silicone anti-glare shield about 1 mm above the edge of the nail.

Duration of treatment for medium infection: Three PACT® MED applications following the PACT® UREA 40 application and then once a month for **3–6 months**.

Between the PACT® MED treatments, apply PACT® UREA 40 daily without a plaster in order to keep the nail soft and to prevent regrowth of nail fungus.





Each infected nail must be illuminated separately, although the gel can be applied at the same time.



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

Treatment of severe infection:

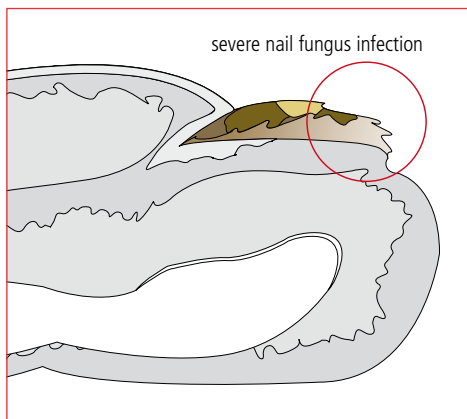
If the nail growth is very slow or stops altogether, treatment leading to a healthy nail is no longer possible.

Other factors that can worsen the prognosis include: infection of the nail matrix, infection due to trauma, diabetic foot syndrome, peripheral arterial occlusive disease (POAD), chronic venous insufficiency, immune suppression.

Treatment of severe infection requires a combination of daily application of PACT® UREA 40 Ointment and regular illumination with PACT® MED over a period of at least 6 months up to a year.

Duration of treatment in case of severe infection: Three applications of PACT® MED after PACT® UREA 40 application and then once a month for at least 6 months. Between the PACT® MED treatments, apply PACT® UREA 40 daily without a plaster in order to keep the nail soft and to prevent regrowth of nail fungus. In the absence of regrowth of healthy nail material, the application of PACT® MED must be increased to 2x monthly. In case of fingernail infection, illumination can also be performed weekly.

Severe infection



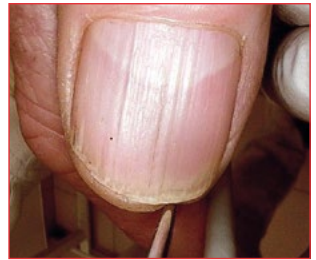
More than $\frac{2}{3}$ of the nail plate, longitudinal infection up to the nail fold, hyperkeratosis (thickening of the nail).

Treatment examples for severe infection

Case: male patient, 80 years, thumb

Medical findings: severe nail mycosis

Initial laboratory diagnosis: *Trichophyton rubrum*, second picture after 4 months, third picture after 10 months



Case: female patient, 60 years, toenail

Medical findings: severe nail mycosis for 10 years

Initial laboratory diagnosis: *Trichophyton rubrum*, second picture after 1 month, third picture after 6 months



(Documentation: Podiatrist Peter Kovar, Stuttgart)

Aftercare

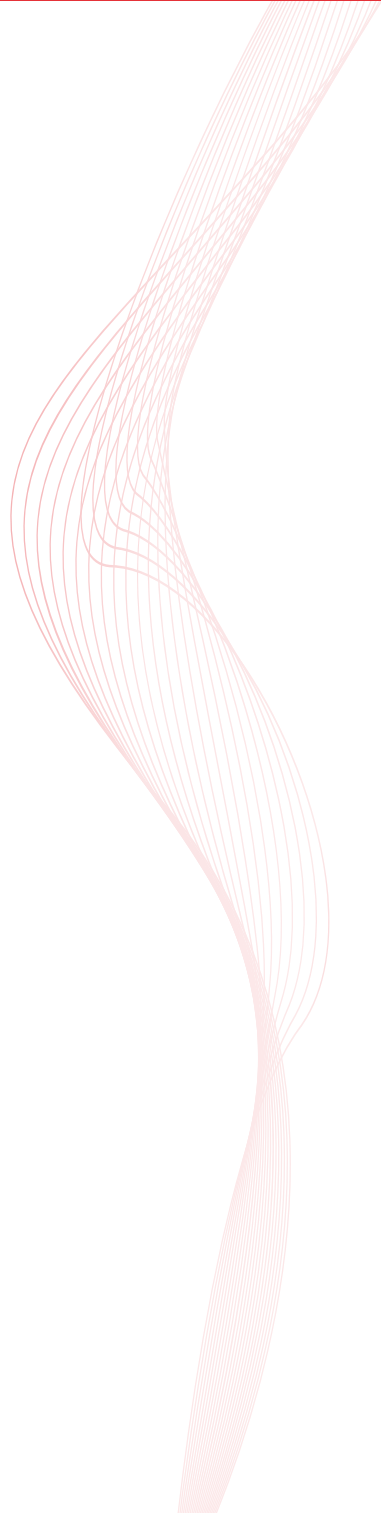
In order to prevent reinfection, regular (daily) application of PACT® UREA 40 Ointment is recommended, apply thinly (without plaster).

This improves the nail structure. PACT® UREA 40 should be reapplied at the first signs of a nail change at the latest.



Note:

Please follow the instructions for use of PACT® UREA 40. With podiatric treatment of the photo-activated therapy, please observe the instructions for use of the Nail Fungus Gel and PACT® MED. The addresses of podiatrists who use the PACT® MED system, as well as forms for the self-payer fungus diagnostics in Germany may be found at www.hahnmedicalsyste.ms.com.





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