

PACT[®] Nail Fungus Therapy

Photodynamic Therapy for nail fungus using light.... safely and gently.

Onychomycosis is a fungal infection of the nail and is estimated to affect up to 1.6 million Australians.^{1, 2} Two currently available treatments include antifungal nail lacquers that are applied daily/weekly and prescription medications.

It can be frustrating to have to apply the lacquers daily/weekly especially considering it takes at least 3 months to see improvement, given the slow growth of toenails. Furthermore, prescribed oral medications can interact with other drugs and can produce adverse effects making them unsuitable for some people.

There is now an alternative.... **Photodynamic Therapy.**

1. Welsh O et al. Onychomycosis, Clin Dermatol 2010 28(2): 151-9
2. Elewski BE. Onychomycosis: Pathogenesis, Diagnosis, and Management, Clinical Microbiology Reviews, July 1998, Vol 11, No 3:415-429

PactMED Set



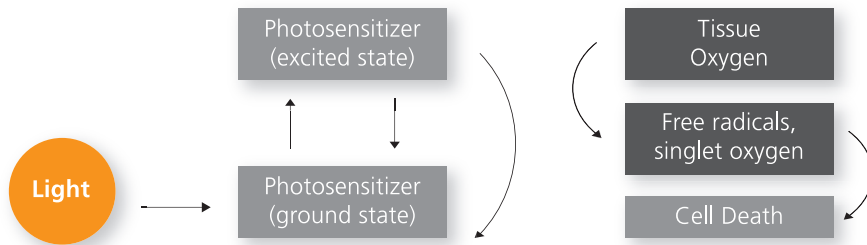
- 1 x PactMED LED.
- 1 x light conductor (optical wave guide)
- 1 x short stand (floor application)
- 1 x telescopic stand (patient chair application)
- 10 x autoclavable anti-glare shields
- 1 x battery pack with charging device
- 1 x tube PACT Nail Fungus Gel
- 1 x practitioner's guide
- 1 x Packet of Patient Information Leaflets
- 1 x Wall Poster

PACT Nail Fungus Gel is available for purchase from Briggate Medical Company



Photodynamic Therapy Explained

PDT is an acronym and a scientific term for photodynamic therapy. The basis of PDT is the interaction of light with photosensitive agents to produce an energy transfer and local chemical effect. Using this method, bacteria, viruses and fungi can be effectively destroyed on the skin surface or nails.



The earliest recorded treatments that exploited a photosensitiser and a light source for medical effect, in this case sunlight, can be dated to over 3000 years ago to ancient Egypt and India. Records suggest the use of topically applied vegetable and plant substances in combination with sunlight to produce photo-reactions in skin which caused a re-pigmentation of de-pigmented skin lesions, as seen with vitiligo.

Reports concerning the prevalence of onychomycosis are conflicting, but estimates ranging from 2-3% to 13% in western populations have been noted.³ In Australia alone, it is suggested that approximately 1.6 million people have a fungal infection of the nails.

Whilst there is currently an assortment of treatment options for onychomycosis ranging from nail lacquers to oral antifungal medications, the challenge of patient compliance in regard to topical antifungals and concerns regarding drug interactions and adverse effects of oral antifungals has resulted in the need for an alternative treatment option. Photodynamic therapy has now been developed and adapted for the successful treatment of fungal nails without damaging side effects.

3. Heikkala H, Stubbs S. The prevalence of onychomycosis in Finland. *Br J. Dermatology* 1995; 133:699-701. Elewski Be, Charif MA. Prevalence of onychomycosis in patients attending a dermatology clinic in North Eastern Ohio for other conditions. *Arch Dermatology* 1997; 133:1172-3.

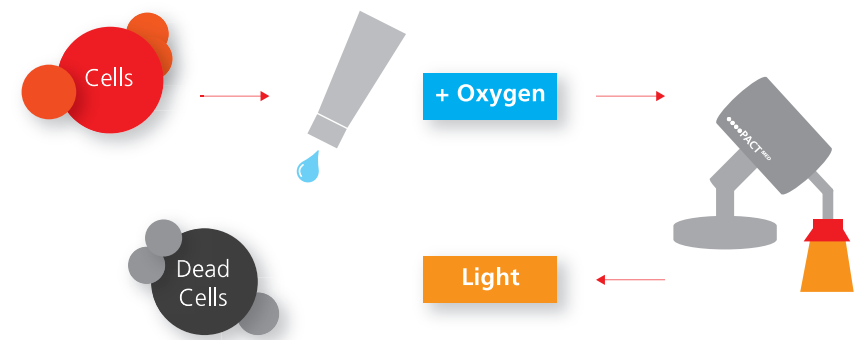
Mechanism of Action

Photodynamic therapy comprises three key components:

- A Photosensitiser - non toxic dye, Phenothiazine such as Toluidine blue (tolonium chloride)
- A light source – LED light
- Tissue oxygen

Photodynamic therapy (PDT) involves the use of photochemical reactions mediated through the interaction of photosensitising agents, light, and oxygen. When the photosensitiser, PACT Fungal Nail Gel is exposed to a specific wavelength of light (630nm) delivered by PactMED LED, it becomes activated from a 'ground' to an 'excited' state. As it returns to the ground state, it releases energy, which is transferred to oxygen to generate reactive oxygen species (ROS), such as singlet oxygen and free radicals. These ROS mediate cellular toxicity and induce fungal cell death without affecting surrounding tissue whose cells are impenetrable by the photo-sensitiser.

PHOTOSENSITISER



Standard treatment regime is as follows:

1 · NAIL DEBRIDEMENT -

The nail must be debrided as much as possible to allow maximum penetration of the gel.



2 · GEL APPLICATION -

Liberal apply the PACT Nail Fungus Gel using a cotton applicator or orange stick, covering the whole nail above and below the nail plate, as well as the nail grooves and in the sulci. The gel can also be rubbed into these areas if need be.



IMPORTANT



Allow the Nail Fungus Gel to remain for at least 10 minutes prior to the light application.

3 · LIGHT APPLICATION -

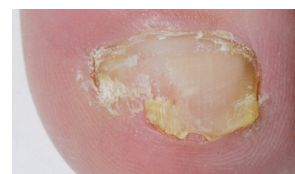
Apply the PactMED LED at a distance of at least 1 cm for 9.5 minutes positioning the anti-glare shield over the nail and in contact with the toe itself.



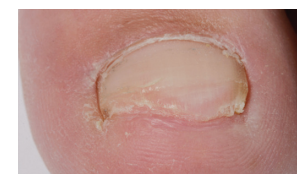
The frequency of treatment should be determined by the severity and duration of the infection, as well as the general health and age of the patient and any co-morbidities.

Treatment Frequency	Mild Onychomycosis 	Severe Onychomycosis 
Initial	3 x 9.5 minutes in 1 week	3 x 9.5 minutes in 1 week
Review	Review after 3 months and repeat as required, or for prophylaxis	Review and repeat treatment after 1 month
Subsequent Review		Review after 3 months and repeat as required or for prophylaxis

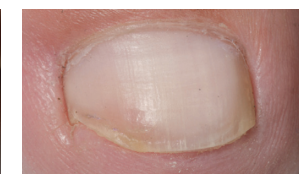
Example of Treatment Progress



Initial Consultation



5 weeks post PactMED treatment



11 weeks post PactMED treatment

Treatment Protocol for Paronychia

- 1 · GEL APPLICATION** - Apply PACT Nail Fungus Gel liberally to the affected area and leave for 1 minute.
- 2 · LIGHT APPLICATION** - Treat with PactMED LED light continuously for between 2 and 5 minutes.

The treatment time can be extended up to 9.5 minutes depending on the severity and duration of the infection. Although one treatment is typically sufficient, in cases of severe and prolonged infection the treatment can be repeated.

Contra-indications and Side Effects

There are no known contra-indications for the PactMED, however it is important to note the ingredients of the gel and identify those patients who may experience an allergic reaction.

The nail retains a blue discolouration that will vanish soon after treatment, however in rare cases it may remain for up to one week.

The effectiveness of the treatment can only be assessed after a period of approximately 3 months due to the time it takes for the nail to grow. If the affected part of the nail fails to grow out and spreads to the base of the nail, application can be repeated and prolonged if required.

For the purpose of prophylaxis after a successful treatment it is recommended to repeat the treatment every 6 months for 9.5 minutes. Note that extended exposure does not have any adverse affects.

Ingredients of the Nail Gel

Water, Propylene Glycol, Natrosol (Hydroxyethyl Cellulose), Potassium Sorbate, Lactic Acid, Tolonium Chloride

Fungal Nail Gel

- Do NOT use if tube is damaged
- Apply using an applicator
- The tube has an expiration date of 3 months after opening

Tips to Prevent Re-Infection

To optimise the success of the PactMED treatment, it is essential to minimise the risk of re-infection.

Some tips include

- Use of a topical anti-fungal solution applied daily
- Regular rotation of patient's shoes for drying and aeration
- Treat shoes with an anti-fungal prior to commencement of treatment and regularly after its completion.
- A UV light sanitiser can be used as an alternative to treat the shoes
- Wash hosiery in hot water and even apply antifungal solution to the washing cycle
- Patients should be encouraged to wear thongs in public showers and swimming centres
- The use of hosiery/socks containing silver can also minimise re-infection
- Disinfect shower floor
- Minimise micro trauma to the nails (which makes the nails more susceptible to infection) by ensuring correct shoe fit
- Patient should not share nail clippers

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