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**PACT® Nail Fungus Therapy**

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

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●●●●● PACT MED

## Photodynamic Therapy for the Treatment of Onychomycosis

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

Maintaining patient compliance with the use of nail lacquers can be challenging with results only visible after 3 months and many in frustration simply give up. Furthermore, prescribed antimycotics may interact with existing medications and produce adverse side 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
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# 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

# Assembly Instructions

1. Insert light conductor into **PactMED LED**.
2. Attach anti-glare shield to light conductor.
3. Insert base of handle into selected stand.
4. To activate LED press the start button.
5. Treatment times can be entered on the control panel and range from 0.5 to 9.5 minutes.
6. A flashing light on the control panel indicates a low battery.

## Please Note

Irradiation level is not affected even when flashing light appears.



1. Start button
2. Light Conductor (optical wave guide)
3. Anti-glare shield
4. Control Panel and display
5. Increase/decrease Irradiation time
6. Irradiation time display
7. Power Supply



5 6

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.

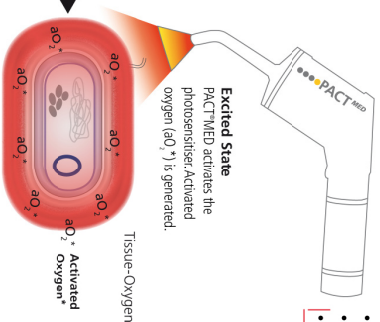
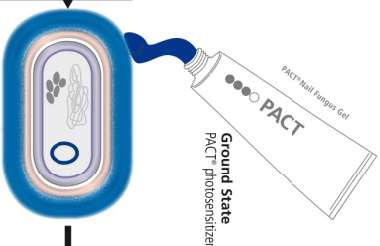
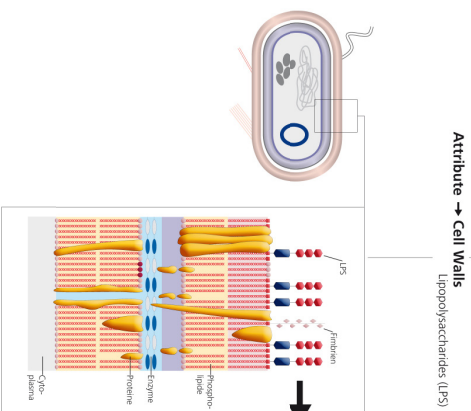
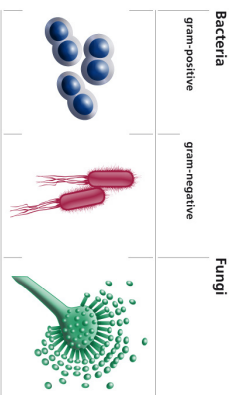
Reports concerning the prevalence of onychomycosis are conflicting, but estimates ranging from 2-3% to 13% in western populations have been noted.<sup>3</sup> In Australia alone, it is suggested that approximately 1.6 million people have a fungal infection of the nails.

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.

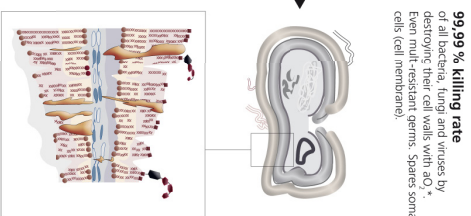
3. Heikkala H, Stubbs S. The prevalence of onychomycosis in Finland. *Br J. Dermatology* 1995; 133:699-701  
Elewski Be, Charif MA. Prevalence of onychomycosis in patients attending a dermatology clinic in North Eastern Ohio for other conditions. *Arch Dermatology* 1997; 133:1172-3.



# Photodynamic Therapy



- PACT®**
- Kills gram-positive and gram-negative bacteria, fungi and viruses similar to the mechanism of the granulocytes in the host response (activated oxygen)
  - Destroys biofilms and cell walls
  - Destroys bacterial lipopolysaccharides, phospholipids etc.
  - Blocks bacteria enzymes and proteinases
  - Reduces bacterial virulence
  - Promotes tissue regeneration and collagen growth

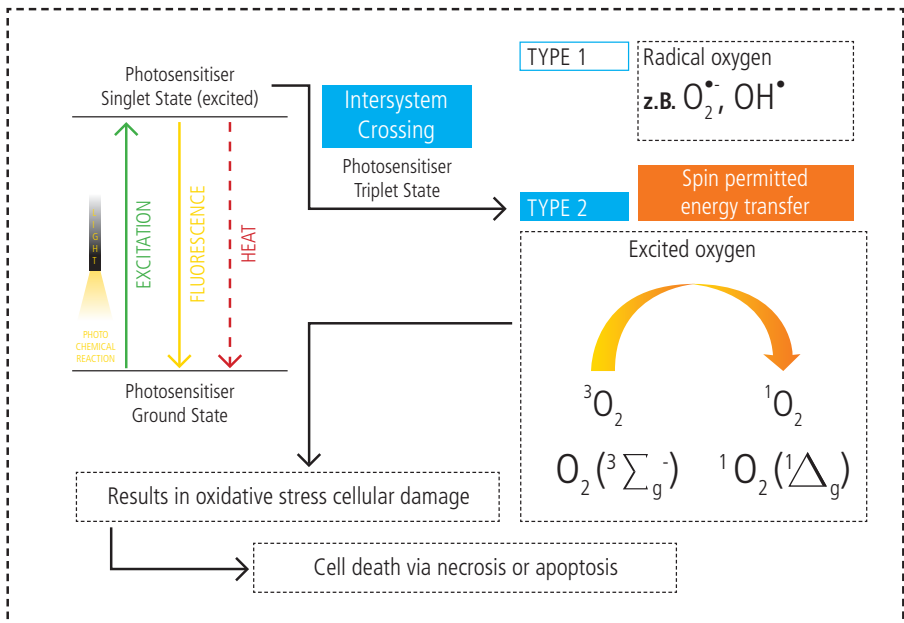


## Photodynamic therapy comprises three key components:

- 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.

## Energy diagram of the photochemical reaction



## Standard treatment regime is as follows:

### 1 · NAIL DEBRIDEMENT -

#### a. Mechanical Debridement

The nail must be debrided as much as possible to reduce the thickness of the nail and therefore allow better penetration of the nail gel and light as well as reducing the fungal load.

#### b. Chemical Debridement

In severe cases and those with nail matrix involvement the PACT treatment can be further enhanced by mild chemical debridement using 40% Urea ointment. Urea ointment is applied to the nail followed by an occlusive dressing for one day. It is then removed and reapplied after a further day when the nail has been exposed. This is repeated for between 1-2 weeks with the ideal outcome being slight softening of the nail.

— Treatment regime to be adapted to individual patient in response to changes to the nail



### 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.



Please see Page 9 for more details regarding Fungus Gel.



### 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.

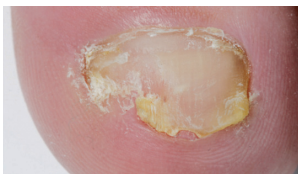


## Frequency of Application

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 
<b>Initial</b>	3 x 9.5 minutes within 1 month	3 x 9.5 minutes within 1 month
<b>Review</b>	Review after 3 months and repeat one application as required, or for prophylaxis	Review and repeat treatment (one application) after 1 month
<b>Subsequent Review</b>		Review after 3 months and repeat one application as required, or for prophylaxis

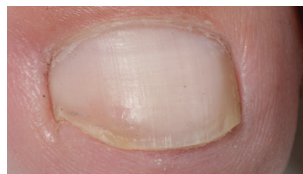
### Example of Treatment Progress



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.



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.

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### 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

<b>Wavelength</b>	620-640 nm
<b>Class</b>	Class IIA (93/42/EEC)
<b>Capacity of the LED</b>	10W
<b>Power</b>	600mW
<b>Treatment Length</b>	0.5 – 9.5 minutes depending on indication
<b>Current Input</b>	Max. 4.5 A
<b>Power Supply</b>	1 x lithium ion rechargeable battery 3.7 V/2000 mAh <i>or</i> 1 x adaptor 100-220V/50-60 Hz
<b>Operating Period</b>	Approximately 30 minutes with fully charged battery
<b>Operating Temperature</b>	10 – 45 °C
<b>Storage Temperature</b>	-5 – 50 °C
<b>Dimensions</b>	55 x 110 x 160 mm

The PactMED system is constantly monitored by software on a micro-controller to ensure it is operating properly. The LED and its current intensity, voltage, temperature and output voltage are all controlled, monitored and in the event a malfunction the system is automatically reset. In the case of an electrical fault an internal fuse provides protection.

### **Important**

- Do not use magnifying glass near PactMED
- Protective goggles are not required to be worn
- Always use the anti-glare shield
- No damage to any tissue can occur even if the maximum treatment length is chosen
- Keep at least 1 cm distance between the PACT and the treatment area
- PactMED should only be operated under the supervision of a qualified medical practitioner

### **Power Supply**

You can use either:

- Lithium ion rechargeable battery 3.7 V/2000 mAh *or*
- Adaptor 100-220V/50-60 Hz

### **Low Battery**

If the display unit flashes during the treatment, the rechargeable battery must be replaced or recharged as soon as possible but treatment may continue.

*Note – At no time is the intensity of the LED affected.*

The battery is fully recharged after 3-4 hours and allows approximately 30 minutes of operating time.



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

The PactMED device can be wiped with moist alcohol swabs or suitable disinfecting products.

The anti-glare shield can be autoclaved at 134 °C.

### **Important**

- Do NOT soak the device and/or attachments
  - Do not use aggressive cleaning products
  - Avoid any contamination to ensure optimal efficiency and lifespan of the device
  - None of the components of the device should be exchanged or serviced by the user. Do NOT open the device and in case of any malfunction please contact Briggate Medical Company.
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### **TGA Certification**

Included as a class IIA medical device

### **Warranty Details**

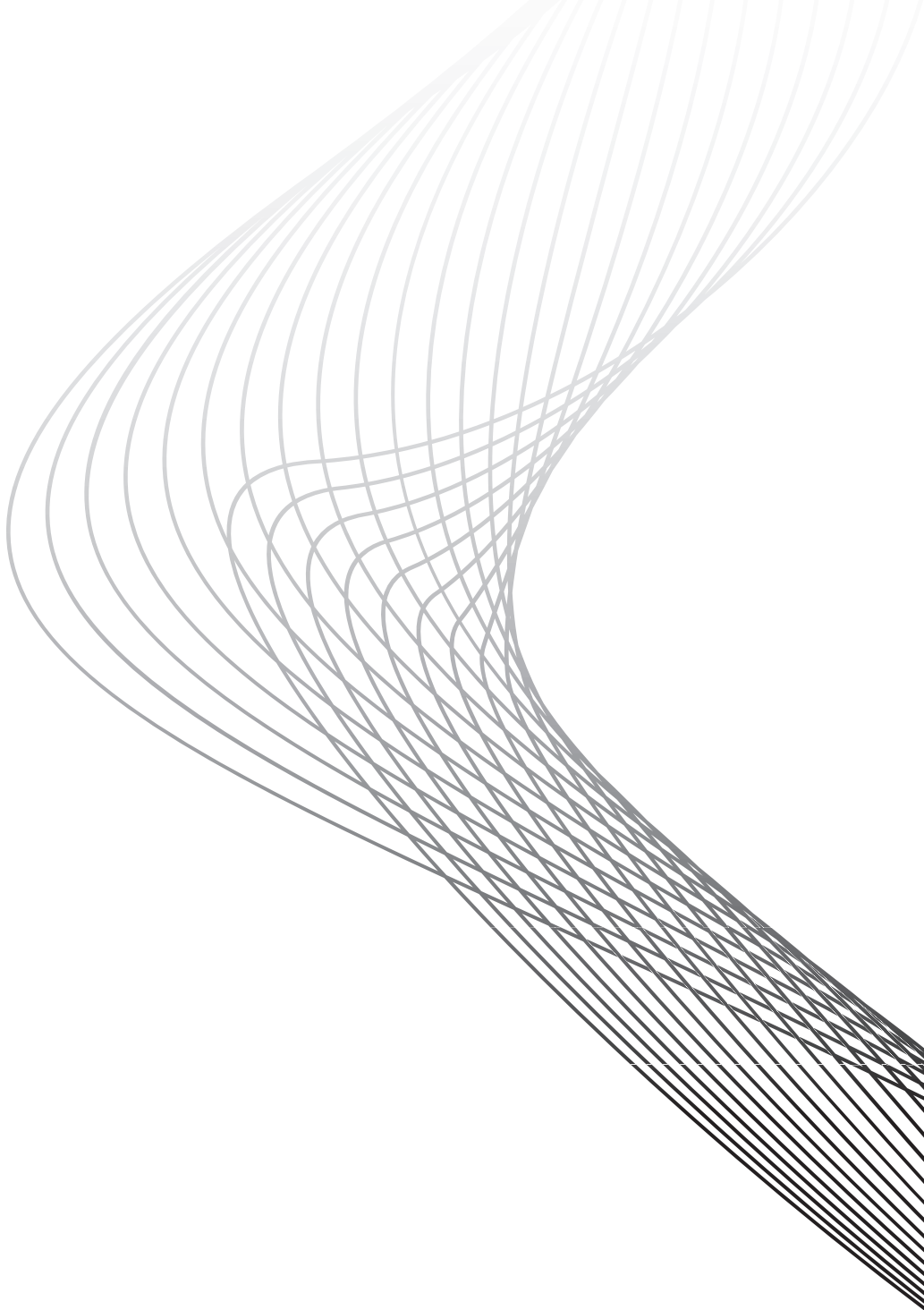
The unit and parts have a warranty of 12 months.

### **Manufacturer**

Cumdente GmbH  
Hahn Medical Systems GmbH  
Paul-Ehrlich-Straße 11  
72076 Tübingen, Germany

### **Australasian Sponsor**

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