Kleresca®

CHANGING DERMATOLOGY THROUGH FLUORESCENT LIGHT ENERGY

Learn more about the technology behind Kleresca®

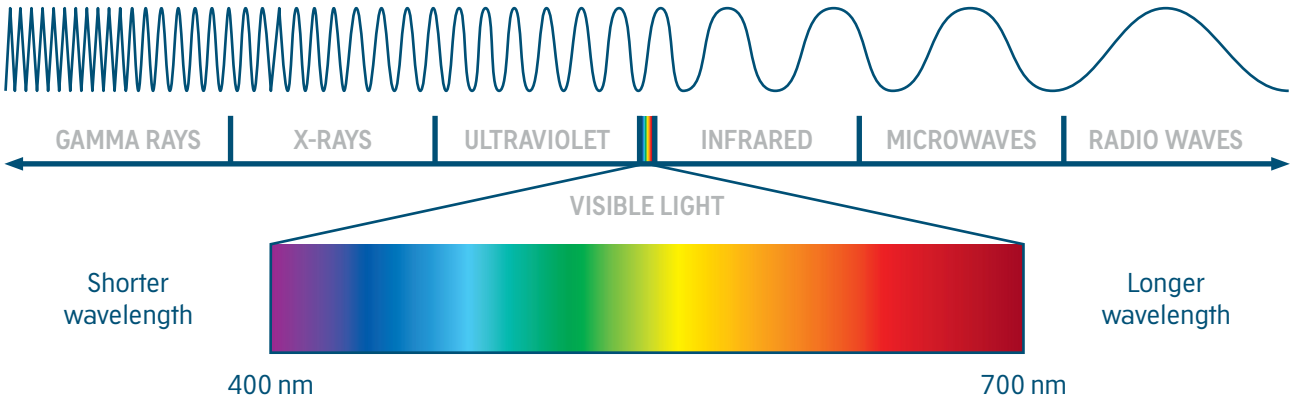
Kleresca®

Innovative technology using Fluorescent Light Energy (FLE)

The Kleresca® platform offers non-invasive treatments for both therapeutic and aesthetic conditions using Fluorescent Light Energy (FLE) to stimulate the skin's own biological processes and repair mechanisms through photobiomodulation[5,25]. Demonstrating high safety and efficacy, our technology triggers documented skin repairing benefits for a number of diseases and conditions[5-9,19,20,27,28].

The importance of light

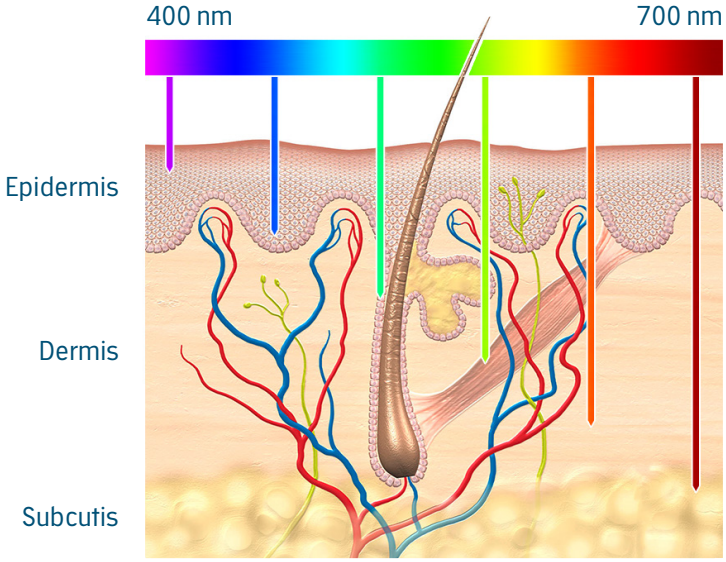
Light is present in our daily life in many processes, like helping us to synthesise vitamin D or allowing us to see. Light is also used in many therapeutic treatments, including dermatology, wound healing, and pain relief. In order for the light to have a biological effect, it must be absorbed by cells and tissues. The following image shows a representation of the light spectrum with special emphasis on the visible light.



The skin is able to absorb visible light (from 400 to 700 nm) which may trigger a biological effect. Visible light will penetrate the skin in different ways depending on its wavelength.

Shorter wavelengths (blue colour) will penetrate only the most superficial parts of the skin (epidermis) whereas longer wavelengths (green, orange, red colour) will penetrate deeper into the tissue.

Depending on the depth reached in the skin, the different wavelengths of light can get access to a variety of biological structures and have different effects[1-5].



Kleresca®

Transforming the skin from within

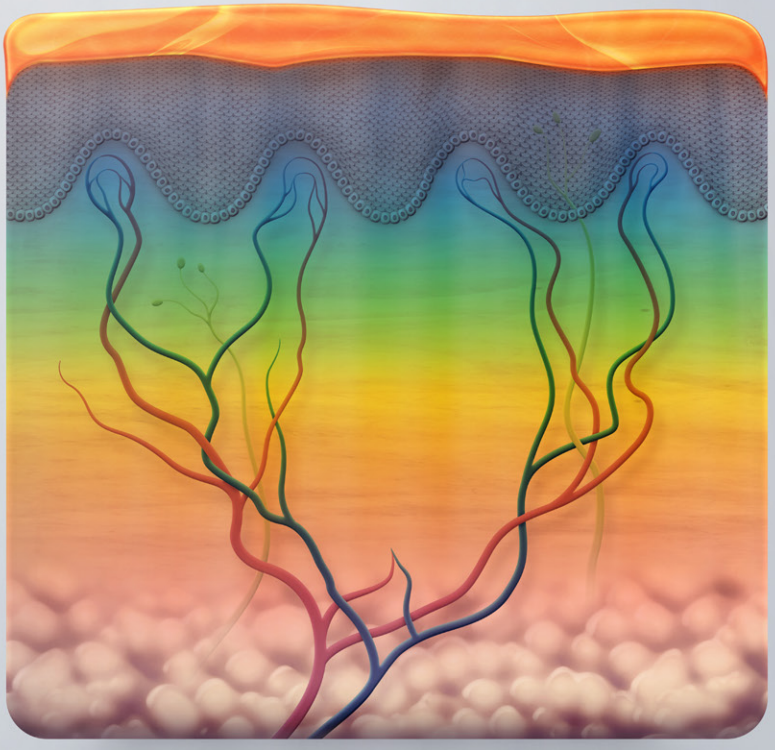
FLE initiates the photobiomodulation process in the skin. This is based on the evidence that photons are able to interact with biological systems, cells and tissues, which consequently induce molecular pathways, modulating several aspects of cell biology[1].

The physiological and therapeutic effects of FLE have recently been explored in several tissues and cells[32]. While the complete cellular and molecular mechanisms are not fully clarified, it is believed to largely affect cellular metabolism, increase adenosine triphosphate (ATP) and modulate reactive oxygen species (ROS). A change in ROS is known to affect transcription factors, responsible for growth, inflammation, cellular proliferation and oxygenation, eventually culminating in augmented tissue repair[33].

The clinical and biological documented effects of FLE include[2]:

- Anti-inflammatory response, especially beneficial for such conditions as acne, rosacea and keratosis pilaris
- Post-interventional inflammation and erythema (e.g. following IPL or laser treatments)
- Increased normalised cell growth for wound healing
- Photorejuvenation
- Scar prevention and recovery
- Increased angiogenesis

More specifically, red and orange light have been shown to induce the dissociation of nitric oxide from the enzyme cytochrome C oxidase, and have been associated with collagen regulation. Yellow light is generally believed to alter ATP production and fibroblast activity. Blue light specifically causes disruption of the endogenous *C. acnes* (formerly *P. acnes*), and green and blue light are also believed to be anti-inflammatory through a shift in cytokine production[1-3]. In addition to these general effects, the various wavelengths are known to penetrate different depths of the skin, gaining access to a variety of biological elements in the skin[2,4].



Graphical representation of FLE penetrating the different layers of the skin

The difference is fluorescent

The Kleresca® technology is based on FLE produced by excited light-absorbing chromophores when illuminated with a multi LED lamp.

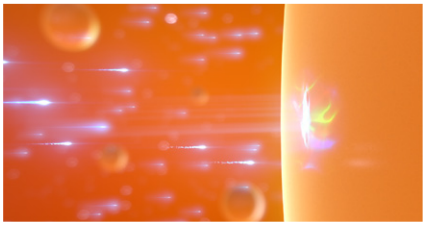
The photo conversion of the gel leads to the production of a dynamic hyper-pulsed multi-wavelength spectrum of FLE through the phenomenon of Stokes Shift[27].

These wavelengths have the capacity to penetrate to various depths of the skin and to stimulate the skin tissues and cells[5].

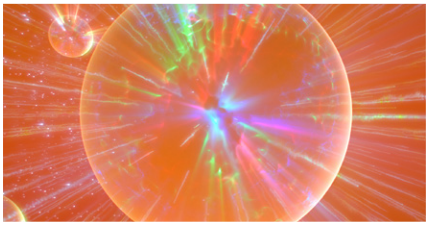
It appears that this hyperfast pulsing of light is the key to the technology's various benefits, like enhancing collagen production and anti-inflammatory effects.

In scientific studies, FLE has shown better outcomes on the treated cells than continuous conventional LED light[5]. Theories for enhanced collagen production with FLE suggest cytochrome C activation increasing mitochondrial energy production leading to downstream activation of various genes for collagen synthesis[1].

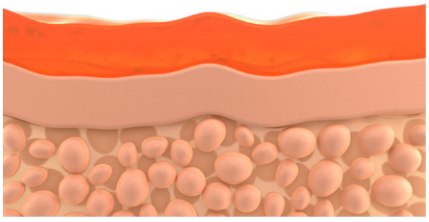
FLE has also been reported to activate nuclear factor kappa-light-chain-enhancer of activated B cell (NF-kB) – the master regulator of inflammation in normal quiescent cells[5].



The photoconverter gel absorbs blue light from Wavemed® FLE

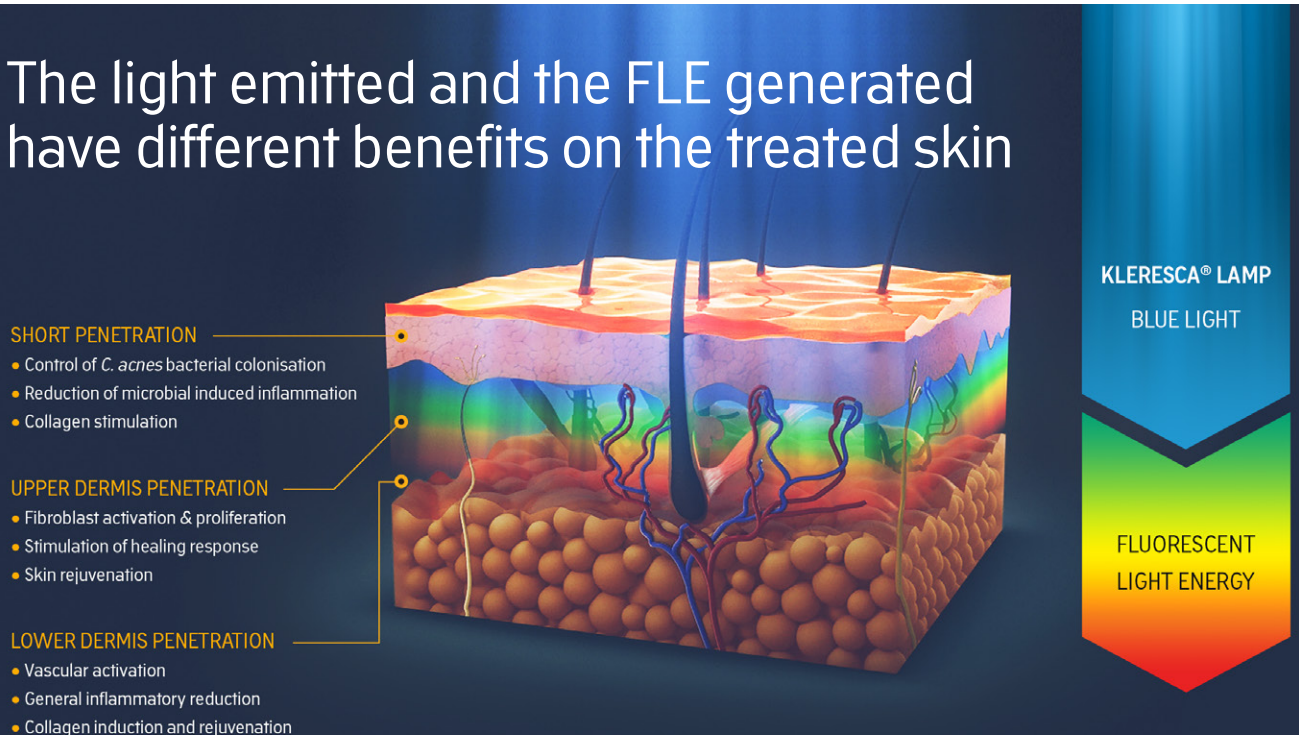


The chromophores convert the blue light into FLE



FLE stimulates the skin at the cellular level

The light emitted and the FLE generated have different benefits on the treated skin



Kleresca® FLE treatments

Kleresca® FLE treatments are based on photoconverter gels, which are non-absorbing formulations containing light absorbing molecules (chromophores)[27].

A thin layer of the photoconverter gel is topically applied on the targeted skin area, and subsequently illuminated with Wavemed® FLE, to create a biophotonic action in which FLE is generated[27].

Afterwards, the exhausted photoconverter gel is fully removed and the skin is cleaned and moisturised[25].

Together, the photoconverter gel and Wavemed® FLE provide a dynamic FLE output, both in terms of wavelength and energy delivered over a pre-defined treatment cycle time of 9 min[5].

No UV light or infrared light is emitted or generated. The FLE spectral output generated ranges from 500 to 650 nm, converting the blue light into green, yellow, orange and red wavelengths of the visible spectrum.

The Kleresca® FLE technology has been shown to modulate both diseases affected and healthy skin, decreasing inflammation and enhancing the skin's overall texture[5-9,19,20,27,28].

Easy and pleasant treatment all year round

As this treatment causes no photosensitivity, it is suitable all year round including summer[9,19,20,27,28]. Patients typically describe the three-step treatment as a pleasant experience. It only takes 9 minutes under the lamp. With little to no-downtime, make-up can be applied immediately after the session[5-9,19,20,27,28].

The skin is cleaned and the Kleresca® Gel is applied.

Illuminated for 9 minutes under the Wavemed® FLE, the gel converts the blue light into FLE that stimulates the skin's own repair mechanisms

The gel is removed and the skin is cleaned and moisturised.

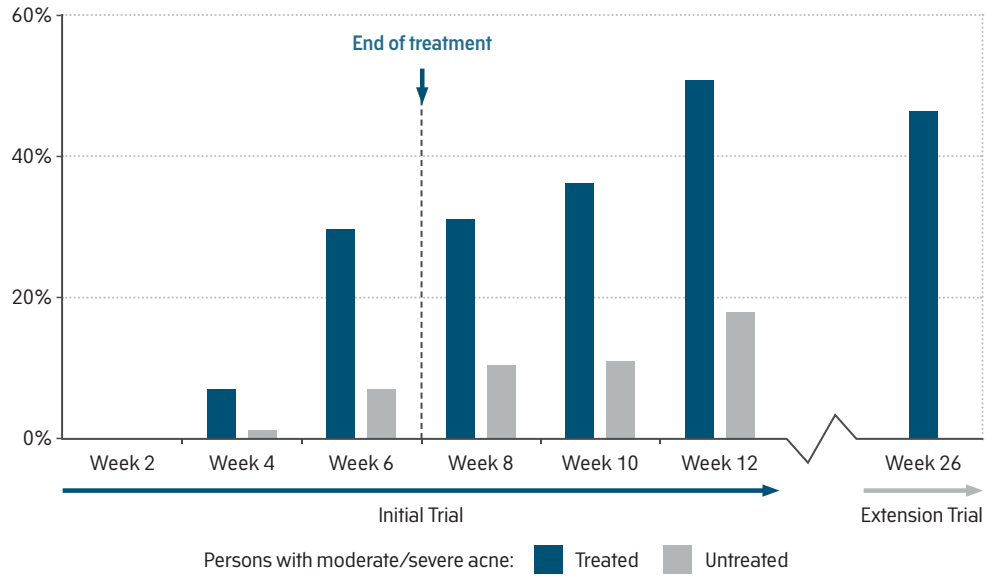
Treatment of acne

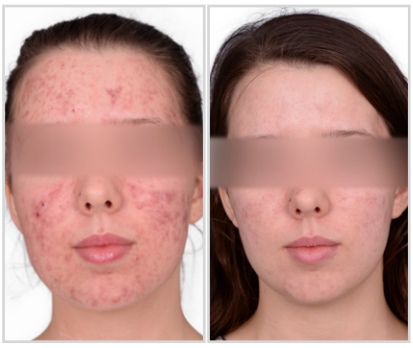
A variety of systemic therapies, both oral and topical, as well as lasers and light treatments have been reported to be effective against acne, although some may pose a range of challenges, like poor tolerability and side effects[3,6].

The Klerescа® FLE technology provides a unique multi-action treatment, targeting at the same time the bacteria responsible for acne (*C. acnes*), reducing inflammation, normalising cell activity and increasing the build-up of collagen, which reduces the signs of scarring[5-7,27].

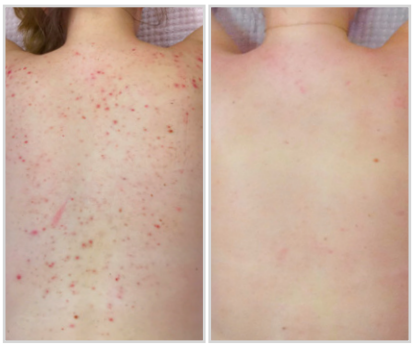
Klerescа® Acne Treatment is the only alternative in the market that uses FLE and is able to treat active acne and acne scarring at the same time[5-9,27].
A gentle, non-systemic and painless technology that provides high efficacy, safety and results that are seen to last up to a year or above. 9 out of 10 acne patients experience noticeable improvements of their skin[5,6]. The treatment not only normalizes the skin but enables it to improve over time, even after the actual treatment has ended[5-7,27].

Proportion of patients with ≥ 2 IGA grades improvement from baseline

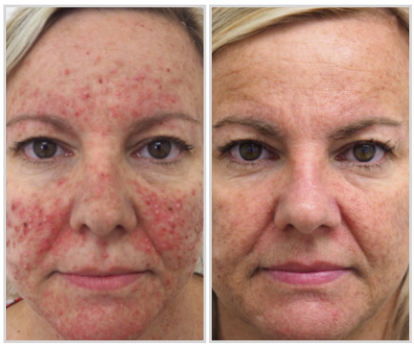




Before After



Before After



Before After

Individual results may vary

Treatment of rosacea

Common treatments of rosacea include topical, oral as well as light-based treatments[26].

Whereas most of the treatments for rosacea aim to combat discrete symptoms of the skin condition, either the vascular effect, the erythema, or the inflammation, not many treatments exist, which seem to influence the various factors involved in the occurrence of rosacea.

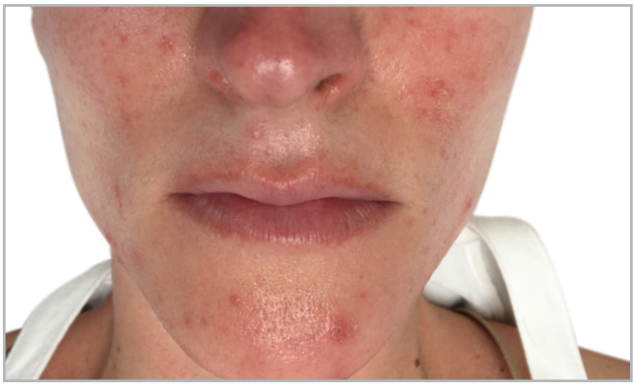
With the increasing knowledge of FLE[1,18,21,23,25], its benefits are becoming more widely documented. These include normalisation of the skin, reduction of inflammation and also stimulation of cells to activate the healing mechanisms that lead to a repairing response of the skin[1,18,21,23,25].

The anti-inflammatory properties and healing response stimulated by FLE have been well documented clinically in both inflammatory lesions of acne vulgaris[6] and in treatment of chronic wounds[22].

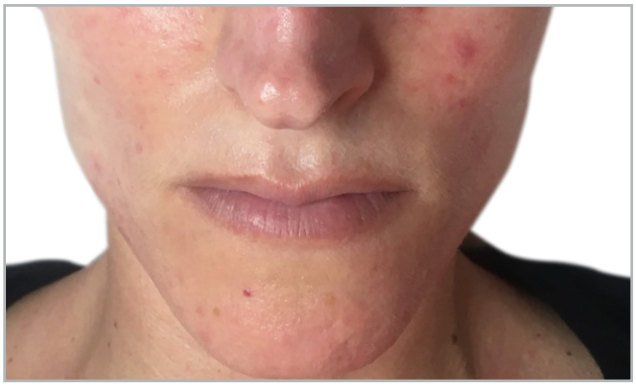
These observations support the pathophysiology related to rosacea.

In addition FLE has been documented to improve microvascularisation, inducing angiogenesis[5]. The ability of FLE to induce healthy vasculature and a normalised de-stressed environment in the skin is beneficial when treating rosacea, in that it improves blood distribution through enhanced lateral blood flow attenuating erythema and blushing.

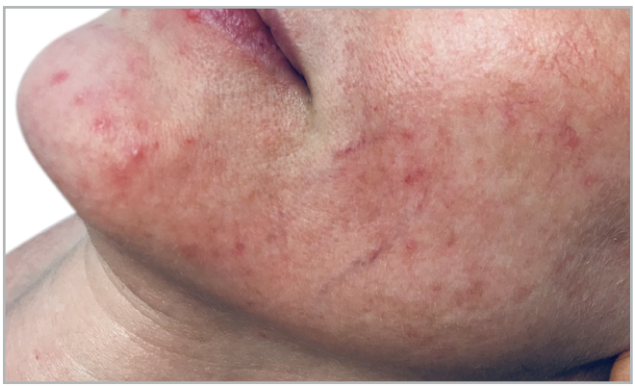
FLE has proven to have fast results in rosacea patients, treating redness, flushing and pimples and reducing burning and stinging sensations[19,20].



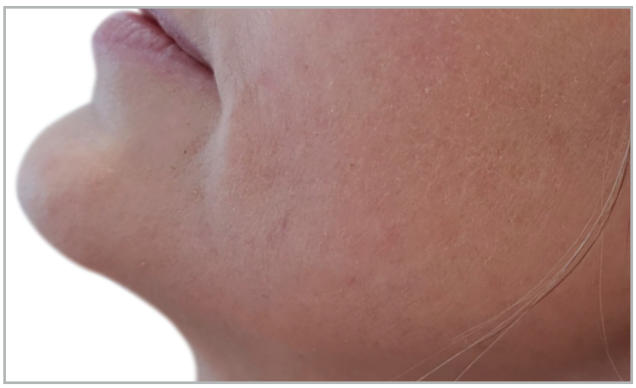
Before



After



Before



After

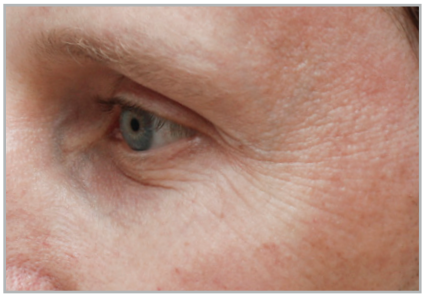
Individual results may vary

Skin rejuvenation

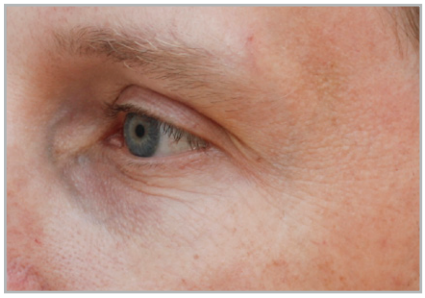
Many different treatment modalities exist to counteract the effects of cutaneous ageing. Ablative methods have been the mainstay for non-surgical facial rejuvenation. In recent years, non-ablative techniques have been developed with the aim of achieving facial rejuvenation without epidermal damage[16]. Photorejuvenation is a novel non-ablative, non-thermal and atraumatic technique that induces collagen synthesis through photobiomodulation[1,17].

Studies with the Kleresca® FLE technology have shown to stimulate the skin's own rejuvenation process. The treatment slows down the signs of skin aging by inducing collagen production up to 400%. This improves pore size, fine lines and overall skin texture, leaving the skin revitalised, firm and glowing.

In addition, in vivo preclinical studies have shown favourable effects of the Kleresca® technology including stimulation of human fibroblast proliferation and increased collagen deposition. In *in vitro* studies, a significant upregulation of up to 400% of collagen production has been seen applying the Kleresca® FLE platform to human fibroblasts[5], which has furthermore been confirmed from biopsies taken during a clinical trial[8].

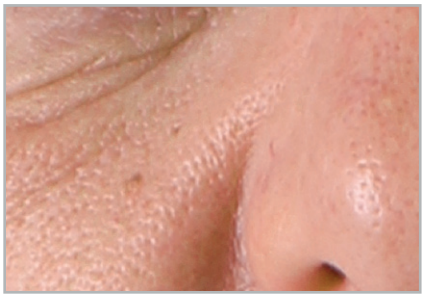


Before

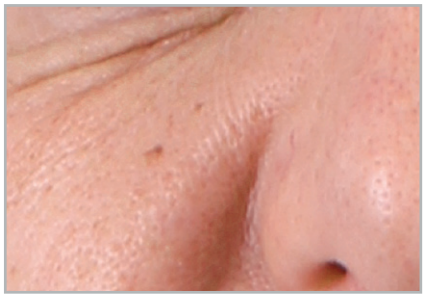


After

Reducing fine lines

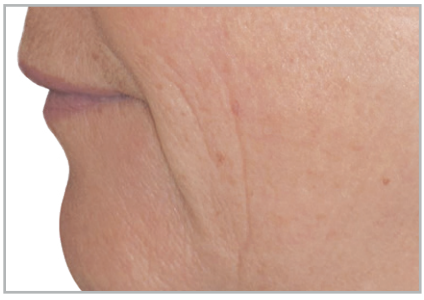


Before

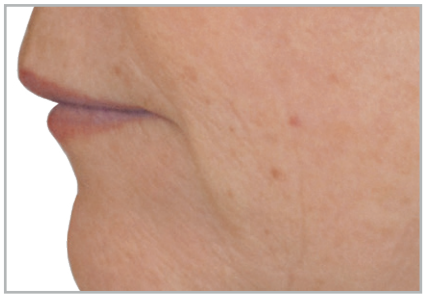


After

Reducing pore size



Before



After

Inducing collagen production

Before and after other procedures

Invasive skin treatments are known for delivering good results, but they can have adverse side effects such as erythema, scaling of the skin, pain and swelling. Some of them lead to long downtimes for the patient[29-31].

The Kleresca® FLE technology treatment can be combined with lasers and other invasive therapies because of its anti-inflammatory effects which can normalise the skin as well as induce collagen build-up[28].

The treatment has a repairing effect at the cellular level due to the activation of the deeper layers of the skin[5,28]. This effect continues over time allowing patients to experience continuous improvements, even after the treatment has ended[6-8].

Kleresca® can be used in conjunction with other non-invasive or invasive techniques, to provide an optimal outcome for the patient[28]. The treatment helps to normalise and smoothen the treated skin due to the collagen build-up, anti-inflammatory effect and normalisation and de-stressing of the skin[28].

Kleresca® prepares and repairs the skin from within, activating skin cells prior to other skin procedures and reducing inflammation, redness and healing time.

SKIN REJUVENATION

- Induces collagen production up to 400%
- Slows down signs of skin ageing
- Improves pore size, fine lines and skin texture

Treatment mode: **Rejuvenation**

ROSACEA TREATMENT

- Treats redness, flushing and pimples
- Reduces burning and stinging sensations
- Fast results

Treatment mode: **Rejuvenation**

KLERESCA® FLE

- Stimulates the skin's own repair mechanisms
- Effective for inflammatory and aesthetic conditions
- Non-destructive, non-systemic and painless

Suitable all year round, including summer

ACNE TREATMENT

- Treats both active acne and acne scarring
- Normalises the skin
- Non-systemic, lasting up to a year and above

Treatment mode: **Therapeutic**

BEFORE AND AFTER OTHER PROCEDURES

- Prepares and repairs the skin from within
- Activates skin cells prior to other skin procedures
- Reduces inflammation, redness and healing time

About FB Dermatology

At FB Dermatology, we aspire to change the fundamentals of dermatology. Our innovative technology represents a unique mode of action that allows us to create a new gold standard within the industry for the benefit of patients worldwide.

Demonstrating high safety and efficacy, the Kleresca® platform offers non-invasive treatments for both inflammatory and aesthetic conditions using Fluorescent Light Energy (FLE) to stimulate the skin's own repair systems in a harmless, non-destructive and painless manner.

With a driven vocation for patient centric cutting-edge solutions, FB Dermatology is currently exploring the use of FLE with a view to developing more non-invasive treatments for a number of skin conditions.

10 countries
and expanding

40+ employees
around the world

390+ partner clinics
worldwide

10,500+ patients
and helping more every day

We are currently involved in scientific partnerships with five universities in Europe, three research centres and approximately 20 clinics to investigate the potential of FLE within present and future therapeutic areas.

We employ a laboratory team researching the impact of FLE on the skin's immune cells as macrophages and in collaboration with selected research partners, FB Dermatology has applied for a Multidisciplinary Research Grant with the Danish Innovation Fund in order to further explore the potential of FLE in inflammatory skin diseases.

Attending a number of international congresses and conferences every year, FB Dermatology is becoming increasingly known in the medical and scientific environment in Europe and other parts of the world. We enjoy the attention of both scientists and clinicians due to the innovative nature of our technology.

KØBENHAVNS UNIVERSITET

HEINRICH HEINE UNIVERSITÄT DÜSSELDORF

Università di Roma Tor Vergata

DTU Technical University of Denmark

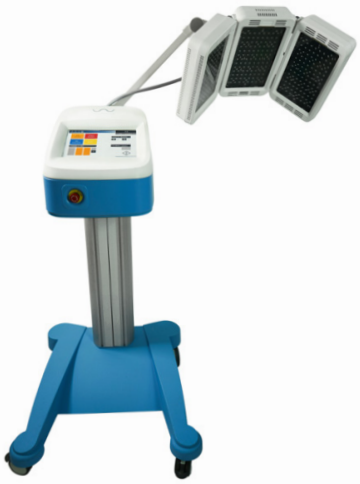
UNIMORE UNIVERSITÀ DEGLI STUDI DI MODENA E REGGIO EMILIA

Kleresca® Acne Treatment

Kleresca® Rosacea Treatment

Kleresca® Skin Rejuvenation

1 kit for 1 session



Wavemed® FLE

Product Name	Box Quantity
Wavemed® FLE	1 floor-standing lamp
Kleresca® Acne Treatment	12 kits per box
Kleresca® Rosacea Treatment	
Kleresca® Skin Rejuvenation	
Operator Goggles	2 pairs per box
Reusable Patient Goggles	1 pair per box
Single Use Patient Eye Patches	50 per box

For scientific and medical support or further product information, please contact:
info@fb-dermatology.com

Kleresca®

Helping people feel good about their skin

INSPIRED BY
PHOTOSYNTHESIS

WORKS AT
CELLULAR LEVEL

FBDermatology

FB Dermatology S.r.l
Via San Giovanni Scafa, SNC
63074 San Benedetto del Tronto (AP), Italy

REFERENCES: 1. Freitas, L. F. de & Hamblin, M. R. IEEE J Sel Top Quantum Electron 22, (2016). **2.** Barolet, D. Semin. Cutan. Med. Surg. 27, 227–238 (2008). **3.** Opel, D. R. *et al.* J. Clin. Aesthet. Dermatol. 8, 36–44 (2015). **4.** Wang, Y. *et al.* Sci. Rep. 6, 33719 (2016). **5.** Edge, D. *et al.* J Clin Aesthet Dermatol (2019);12(5):E61–E68. **6.** Antoniou, C. *et al.* Int. J. Dermatol. 55, 1321–1328 (2016). **7.** Nikolis, A. *et al.* Int J Dermatol. 57(1):94-103 (2018) **8.** Nikolis, A. *et al.* Clin. Cosmet. Investig. Dermatol. 9, 115–125 (2016) **9.** Mahendran, A. et l. Phottodermatol Photoimmuno Photomed, 1-3 (2018) **10.** Ashkenazi, H. et l. FEMS Immunol. Med. Microbiol. 35, 17–24 (2003). **11.** Borelli, C. *et al.* Acta Derm. Venereol. 86, 316–319 (2006). **12.** Elman, M. & Lebzelter, J. Dermatol. Surg. 30, 139–146 (2004). **13.** Goldberg, D. J. & Russell, B. J. Cosmet. Laser Ther. 8, 71–75 (2006). **14.** Papageorgiou, P. *et al.* Br. J. Dermatol. 142, 973–978 (2000). **15.** Chang, S. E. *et al.* Dermatologic Surg. 33, 676–679 (2007). **16.** Sanclemente, G. *et al.* J. Eur. Acad. Dermatology Venereol. 25, 49–58 (2011). **17.** Barolet, D. *et al.* J. Invest. Dermatol. 129, 2751–9 (2009). **18.** Dungel, P. *et al.* Lasers Surg. Med. 46, 773–780 (2014). **19.** Braun, S. A. & Gerber, P. A. Int. J. Dermatol. 1–2 (2017) **20.** Sannino, M. *et al.* Clin Case Rep; 00:1-6 (2018) **21.** Mignon, C. *et al.* Sci. Rep. 7, 1–14 (2017). **22.** Nikolis, A. *et al.* Chronic Wound Care Manag. Res. 3, 101–111 (2016). **23.** Rohringer, S. *et al.* Sci. Rep. 7, 1–11 (2017). **24.** Avci, P. *et al.* Semin. Cutan. Med. Surg. 32, 41–52 (2013). **25.** Hamblin, M. R. & Demidova, T. N. Proc SPIE 6140, 1–12 (2006). **26.** Zuuren, E. *et al.* Cochrane Database Syst. Rev. (2015). **27.** Jalili, A. J Ästhet Chir. 2018. Early online 20 February. **28.** Scarcella *et al.* Clinical Case Reports 00:13 (2018). **29.** Alexiades-Armenakas MR *et al.* J Am Acad Dermatol. 58(5):719-37 (2008). **30.** Goel, A. *et al.*. Indian J Dermatol Venereol Leprol;77(3):369-379 (2011). **31.** Raulin C., *et al.* Lasers Surg Med.;32(2):78-87 (2003). **32.** Jagdeo J *et al.* Lasers Surg Med. January 22, (2018). **31.** Chung H *et al.* Ann Biomed Eng.; 40(2): 516–533 32 (2012). **32.** Hamblin MR & Hamblin M. AIMS Biophys.;4(3):337-361 (2017). **33.** Chung JH, *et al.* J Invest Dermatol.;117(5):1218-1224 (2001). **34.** Chen AC-H *et al.* PLoS One.;6(7):e22453 (2011). **35.** Bhate, K. *et al.* Br J Dermatol. 2013; 168:474-485. **36.** Thielitz, A. *et al.* Am. J. Clin. Dermatol. 2008, 9, 369–81

Learn more at www.fb-dermatology.com