

LUSTRE Pure Light

Instructions for Use



LUSTRE Pure Light

Welcome to LUSTRE Pure Light treatment for Acne

LUSTRE Pure Light harnesses wearable blue light technology to destroy the P.acnes bacteria within the skin's surface. This hands free, wearable technology delivers blue light of the correct wavelength to provide results in only 20 minutes a day.

Recommended by dermatologists and clinically proven, blue light eliminates spot-causing bacteria, while being gentle on the skin.

Indication for use

The LUSTRE Pure Light treatment for acne is indicated for the treatment of mild to moderate inflammatory Acne.



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Ambicare is an ISO 13485:2016 certified company

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What's in the box?

LUSTRE Pure Light treatment head



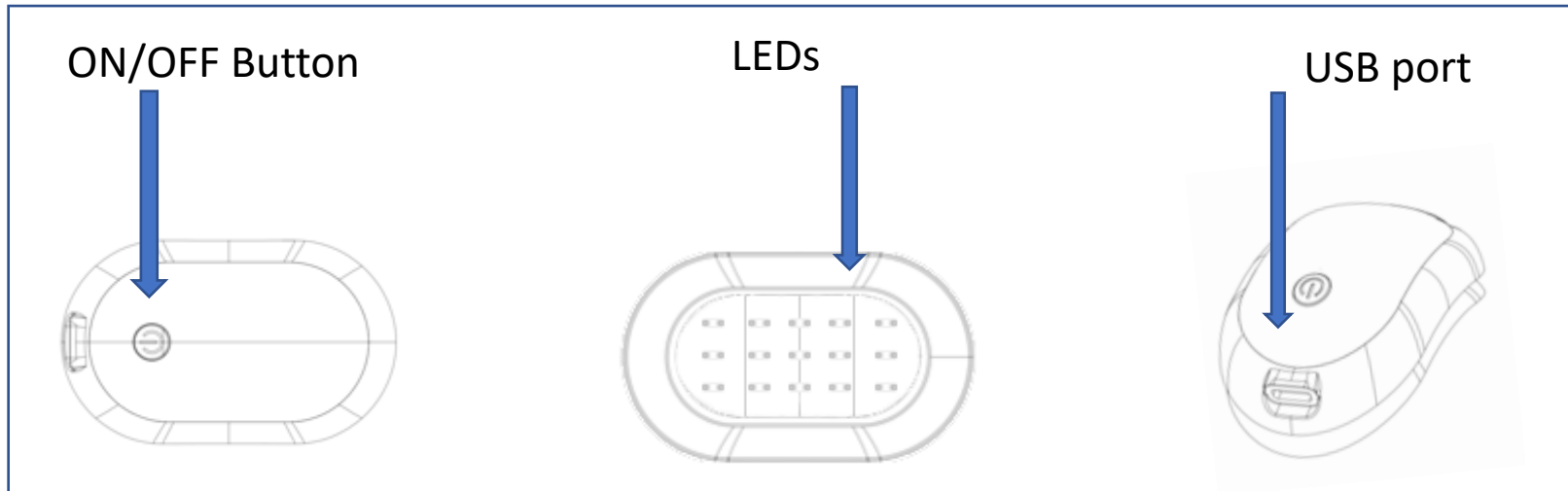
Charger Cable



LUSTRESTRIPS



Instruction Manual



How LUSTRE Pure Light Works

It is recommended that LUSTRE Pure Light treatment for acne is used every day for 20 minutes to achieve the best results.

Each person is different, but if LUSTRE Pure Light is used as recommended, an improvement may be seen from 2 weeks.

Clinical evidence has shown that the best results are seen after 8-12 weeks. ^(1,2,3)

LUSTRE Pure Light delivers safe, visible blue light at a wavelength of 415nm which has been clinically proven to destroy the bacteria that causes spots. With regular use, LUSTRE Pure Light can control the levels of P.acnes reducing the number of new spots forming.

Before you start treatment

LUSTRESTRIPS

Some people have a skin type which is more sensitive to the normal level of adhesion that can be found in the LUSTRESTRIPS. These are the strips which are used to attach LUSTRE Pure Light to the skin.

The best way to check whether your skin is more sensitive is to carry out a short test before your first treatment.

This is done by attaching LUSTRE to your inner forearm, just below the elbow. The LUSTRE treatment head should be left in place for at least 10 minutes before being removed carefully as described below. If there is any discomfort, then we recommend applying a very small amount of moisturising cream to the skin before attaching LUSTRE next time and this will normally solve the problem.

The best way to remove LUSTRE is by lifting it at one edge and peeling it off very slowly. It is also important to note that the device should not be left on any one treatment area for longer than 20 minutes in each treatment.

How to Use LUSTRE Pure Light

1. Charging - Connect the supplied charging cable to the LUSTRE Pure Light. Insert the charging cable into a suitable USB port delivering 5 volts DC at 2 amp. It is recommended that the device is charged using an IEC60601-1 compatible mains adaptor which can be purchased from www.lustrepurelight.com as an accessory. The ON/OFF button will turn green when LUSTRE is fully charged. LUSTRE will provide three 20 minute treatments when fully charged. Do not start a treatment if the ON/OFF button is red as this signifies the battery needs charged.
2. Ensure skin is clean and dry and all make up is removed before treatment, unless your pre-test had indicated the need for a small amount of moisturiser to avoid skin irritation by the adhesive.
3. Attach a LUSTRESTRIP to LUSTRE.



Step 1



Step 2



Step 3

Step 1 – Unpeel from backing.
Step 2 – Place the exposed side of the strip onto the flat surface of LUSTRE and press down.
Step 3 – Peel the top layer of backing paper from the strip.

How to Use LUSTRE Pure Light

1. **Starting treatment.** Place LUSTRE over the treatment area and press down until it feels secure. Press the ON/OFF button for 1 second to begin treatment.
2. LUSTRE will turn off automatically after 20 minutes. A short beep will signal the end of treatment. If you need to turn it off during treatment, press the ON/OFF button for 1 second.
3. To remove LUSTRE from the treatment area carefully and very slowly pull the LUSTRESTRIP using the adhesive strip removal tab.
4. **After treatment.** Carefully pull the LUSTRESTRIP from LUSTRE and discard. Each LUSTRESTRIP should only be used once. This is recommended to prevent cross infection to other areas of skin.

Contraindications, safety and warnings

Read all of the instructions before using LUSTRE Pure Light. Please consult your healthcare provider before using LUSTRE if you have been prescribed any medication for Acne.

Contraindications

Do Not use LUSTRE Pure Light if you are pregnant or may be pregnant.

Do Not use LUSTRE Pure Light if you have a history of porphyria, solar urticaria, chronic actinic dermatitis, photosensitivity.

Do Not use LUSTRE Pure Light over any suspicious or cancerous lesions.

Do Not use LUSTRE Pure Light if you are taking Amiodarone.

Do Not use LUSTRE Pure Light if you are taking any photosensitising treatment.

Do Not use LUSTRE Pure Light over or near a recent steroid injection.

Do Not use LUSTRE Pure Light on children under 13 years old.

Do Not use LUSTRE Pure Light if you suspect that you have had an adverse/allergic reaction.

Warnings

The operator is considered the patient.

Do Not place LUSTRE Pure Light over the eyes, or where the light will shine into the eyes during treatment.

Always keep LUSTRE Pure Light away from water and moisture.

Never insert objects into the openings of the LUSTRE Pure Light.

Never use LUSTRE Pure Light if it appears damaged or if any of the power cables appear damaged.

Never disassemble LUSTRE Pure Light.

Do Not allow any fluid to enter LUSTRE Pure Light at any time. If this happens do not use.

Under normal use the LUSTRE Pure Light will not exceed a temperature of 43°C.

Keep the device out of reach of children.

Contains a cable that may pose a risk of strangulation.

The LUSTRESTRIPS should always be carefully removed to help avoid damage to the skin.

Care

Cleaning

LUSTRE Pure Light is not waterproof. If the LUSTRE requires cleaning at any time, use a soft dry cloth or a cleansing wipe.

Do not allow any fluid to enter any part of LUSTRE, this includes cleaning detergent. If this happens do not use.

For hygiene reasons do not share LUSTRE with anyone else.

The cleaning of LUSTRE shall be capable of being performed by the operator in the home healthcare environment.

Disposal

Disposal

Waste Electrical and Electronic Equipment (WEEE). Do not dispose of the device with normal domestic waste at the end of its life.

Please take it to an official recycling point to be disposed of correctly.

In order to recycle this device you can return it to Ambicare Health Ltd.

Contact Info

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Specifications

Product Name: LUSTRE Solo treatment for acne

Model Number: PR3005

Operating Wavelength: 415nm +/- 15nm

Operating Temperature / Humidity:

10°C to 30°C / 20% to 85%

Operating Irradiance: 5mw/cm²

Storage and Transport Temperature / Humidity:

-5°C to 60°C / less than 85%

Mains Electrical Input: If using a mains adaptor, it is recommended that the device is charged using an IEC60601-1 compatible mains adaptor delivering 5VDC/2A maximum

Life of the Device: The expected service life of the LUSTRE Solo device is 2 years

References

- 1** Phototherapy with blue (415nm) and red (660 nm) light in the treatment of acne vulgaris. Papageorgiou et al British Journal of Dermatology 2000; 142:973-978.
- 2** An open study to determine the efficacy of blue light in the treatment of mild to moderate acne. Morton et al. Journal of Dermatological Treatment. 2005; 16:219-223.
- 3** Clinical and usability study to determine the safety and efficacy of the Silk'n Blue Device for the treatment of mild to moderate inflammatory acne vulgaris. Michael H. Gold, Julie Biron & Whitney Sensing. Journal of Cosmetic and Laser Therapy, 2014; 16:108-113.

Troubleshooting

Problem	Possible Cause	Action Required
My LUSTRE will not turn on	No power	Charge the device until the control button is green and then try to turn on again. We advise that the LUSTRE is recharged following every treatment session to ensure sufficient power for the next session.
My LUSTRE beeped 3 times	If LUSTRE exceeds 43°C the unit will turn off	Ensure the LUSTRE is not covered by anything e.g. clothes when in use. If you are using the LUSTRE for consecutive treatments allow a 10 minute gap between treatment times. If problems persist, please contact info@ambicarehealth.com or call 01506 592239.

For a full list of troubleshooting and FAQ please visit www.lustrepurelight.com

Warranty

LUSTRE Pure Light treatment for acne is warranted to be free from defects in material and workmanship for a period of 12 months from its original purchase date under normal use. This warranty extends only to the original retail purchaser with original proof of purchase and only when purchased from an authorised retailer or reseller.

If the product should become defective within the warranty period, contact the retailer that you purchased the device from.

This warranty does not cover products damaged by:

- **Accident, misuse, abuse or alteration.**
- **Use with unauthorised accessories or use other than as instructed.**
- **Connecting to incorrect current and voltage.**

To register your product and be kept up-to-date with new and exciting developments from the LUSTRE team, please take a moment to sign up on our website www.lustrepurelight.com

To complete your registration online you will need to enter your LUSTRE batch number.

Symbol Glossary



Refer to operating Instructions



Class II equipment – provides double Isolation to protect against electric shock

Degree of protection – IP44

IP44

Protection against penetration by solid particles with diameters larger than 1 mm. Protection against splashing water.



TYPE BF

Type BF Applied Part

LOT

Batch/Lot/ID Number

This is the unique identifying number for each batch



Expiry date of the LUSTRESTRIPS



WEEE Compliance

REF

Catalogue number



Manufacturer



Quantity of LUSTRESTRIPS



Keep Dry



Do not reuse – single use



Store in a clean dry area up to 24°C - LUSTRESTRIPS

General Safety/EMC and Electrical Information for the LUSTRE Pure Light

General Safety/EMC and Electrical Information for the LUSTRE Pure Light Device

1. General Safety

1. 1. LUSTRE Pure Light is an electrical device, which under certain circumstances could present an electrical shock hazard to the user.

1.2 EN 60601-1:2006

1.2.1 Protection against electrical shock – Class II

1.2.2 Degree of protection against electrical shock – Type BF Applied Part

1.2.3 Protection against splashing water – IP44

1.2.4 Not suitable for use in the presence of flammable anaesthetic mixture with air or with oxygen or nitrous oxide

1.3 EMI/EMC

1.3.1 Compliance with standard EN 60601-1-2:2015

1.4 LED lighting (Blue Light)

1.4.1 Compliance with standard EN62471:2008

For more info regarding EMC consult www.lustrepurelight.com

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