noctura 400

Sleep Mask

Instructions For Use

Light Therapy for
Diabetic Retinopathy

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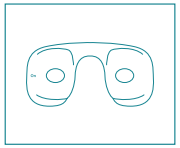
Pack Contents

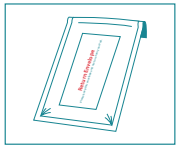
Noctura carry bag, 1x

Fabric Mask, 1x



Pod, 1x

Pod packaging, 1x



Return packaging, 1x

Instructions for Use, 1x

Pod wipes, 4x
(including 3 for general use and 1 to be kept to clean the mask before return)

If any item is missing please contact your Noctura 400 supplier helpline.

Noctura 400

Read all of this leaflet carefully before you start using Noctura 400 because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your clinical provider.
- Do not pass this therapy onto others to use. It may harm them, even if their signs of illness are the same as yours.
- There are no known serious adverse effects related to use of Noctura 400. The following mild adverse effects have been recorded in a small number of patients; general mask discomfort, intolerance to light, sleep disturbance. If you experience any side effects, talk to your clinical provider. This includes any possible side effects not listed in this leaflet.

Notes to User and/or Clinician

To achieve the maximum benefit from Noctura 400 and to avoid any potential hazards it is important that this device is used in accordance with the instructions laid out in this manual.

Any serious incident that has occurred in relation to Noctura 400 should be reported to the manufacturer and the national competent authority in which the user and/or patient is established.

Overview

Noctura 400 is designed to deliver a precise level of light therapy during the hours of sleep in order to treat Diabetic Retinopathy. The Pod is programmed to administer the light each night as part of a continuing therapy. **The device will only operate during a predefined window for a period of 12 weeks, as indicated on the label on the outer packaging of the Pod.** At the end of the allocated period the Pod must be returned for analysis. To continue the treatment, a replacement mask will be required.

What Noctura 400 is and what it is used for

Indication for Use: Noctura 400 is a Class IIa medical device that is CE certified. It is a safe, non-invasive treatment for Diabetic Retinopathy and Diabetic Macular Oedema.

Contraindications for Use

- **DO NOT** use Noctura 400 to treat any condition other than that stated in the indication for use. Noctura 400 has not been tested for any other conditions.

- **DO NOT** use Noctura 400 if you have been diagnosed with Glaucoma until you have consulted your clinical prescriber.

- Noctura 400 is **NOT** recommended to be used with the following types of Glaucoma: Acute Angle-closure Glaucoma and Neovascular Glaucoma. The safe use of Noctura 400 with Acute Angle-closure Glaucoma and Neovascular Glaucoma has NOT been tested and the risk is unknown.

- **DO NOT** use Noctura 400 if you have severe sight restricting Cataracts or Corneal Opacity until you have consulted your clinical prescriber. In severe cases of Cataracts or Corneal Opacity the effect from Noctura 400 may be reduced.

- **DO NOT** use Noctura 400 if you have Symptomatic Diabetic Keratopathy. The safe use of Noctura 400 with Diabetic Keratopathy has **NOT** been tested and the risk is unknown.

- **DO NOT** use Noctura 400 if you are pregnant, or if you are planning to become pregnant. The safety for pregnant women has **NOT** been tested and the risk is unknown. If you do become pregnant when using Noctura 400 **STOP** using the device as soon as you are aware, and inform your clinical prescriber.

- **DO NOT** use Noctura 400 if you have an eye infection or are suffering with discharge from the eyes. Seek medical attention.

- **DO NOT** use Noctura 400 if you have an open cut on the face that is in direct contact with the sleep mask.

- **DO NOT** use Noctura 400 if you are sensitive to light. If you use Noctura 400 and you are sensitive to light you may cause a severe skin reaction.

- **DO NOT** use Noctura 400 if you are known to be sensitive to the materials mentioned on the fabric mask label. If you use the Fabric Mask and are sensitive to the materials, you may cause a skin reaction. Stop use if a reaction occurs.

- **DO NOT** use Noctura 400 if you are taking drugs that may make you sensitive to light.

Warnings and Precautions

- Noctura 400 should be used in accordance with these instructions. This device should only be used under the guidance of a qualified medical professional such as an ophthalmologist, optometrist or GP.

- Current treatment must continue whilst using Noctura 400, unless otherwise prescribed by a clinician.

- Do not use if the packaging has previously been opened, or if the product has been damaged.

- Noctura 400 is powered by batteries sealed inside the Pod. Do not attempt to recharge or replace the batteries.

- Do not expose Noctura 400 to excessive heat and keep clean and dry at all times.

- Noctura 400 should not be sterilised, autoclaved, or flushed with water or any other fluids.

- Noctura 400 should be removed before getting out of bed to avoid the risk of falling.

- The Sleep Mask is suitable for use in the home healthcare environment. High electrostatic

discharge may trigger the sleep mask to reset and turn off during use, however it should return to normal function after being re-started, if a re-set occurs. More EMC information can be found on the website.

Website:
www.noctura.com/noctura400/patientinformation
Username/Password: drmask400

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

- Portable RF communications equipment (including mobile phones and peripherals such as antenna cables and external antennas) should be situated no closer than 30 cm (12 inches) from any part of the sleep mask. Otherwise, degradation of the performance of this equipment could result.

- Noctura 400 is intended as a single-patient use device.

- Any unauthorised modifications to the equipment may result in hazards.

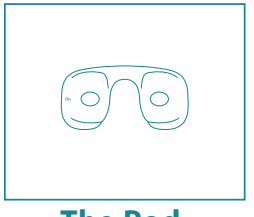
Instructions for Use

Noctura 400 is to be worn during sleep hours, and is programmed to match your normal sleep cycle for up to 8 hours per night across a 12 week period, after which time it will automatically switch off and a new Noctura 400 will be required.

Although the mask will stay activated for 8 hours every night, you only need to wear the mask while you are sleeping, even if this is for less than 8 hours.

1 Remove the Noctura 400 Sleep Mask components from their packaging.

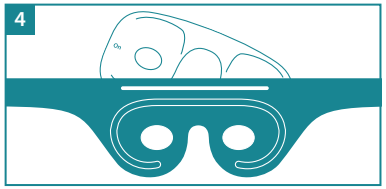
2 Noctura 400 is supplied in two parts - a light-emitting unit or 'Pod' which is housed inside a soft feel 'Fabric Mask'.



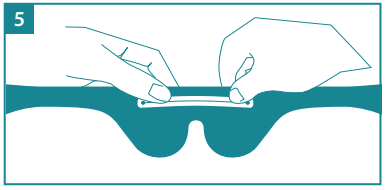
The Pod

The Fabric Mask

3 The Pod is pre-programmed to operate only during the operational window, and to deliver a precise level of light each night for the lifetime of the Pod, as written on the outer packaging of the Pod.

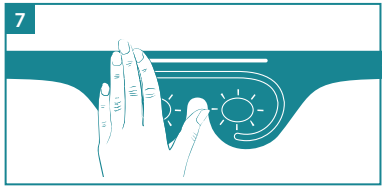


Place the Pod into the Fabric Mask by inserting into the pocket.

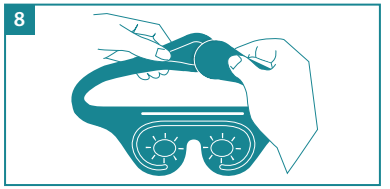


Ensure that the Pod is located fully inside the Fabric Mask and seal the pocket closed using the hook-and-loop touch fastener located inside the pocket opening.

6 Each night, when you are ready to go to bed, remove any make-up, false eyelashes, or anything that will interfere with mask contact to the face.



Switch the mask on by gently covering the left side of the mask with the palm of your hand for up to 5 seconds. This is where the 'On' sensor is located. OLEDs will activate, as shown in the schematic above. If the mask is not used within 3 minutes of being activated, the lights will turn off automatically.



Secure the head strap using the hook-and-loop touch fastener. The strap should be adjusted until comfortable and should not be too tight or too loose.

You are now ready to go to sleep wearing the Sleep Mask.

Nightly Use

It is not necessary to remove the Pod from the Fabric Mask once it is inside, except for cleaning.

If you remove the Noctura 400 Sleep Mask in the first 15 minutes of use, the lights will go out after 3 minutes. Restart by following from step 7.

After 15 minutes of continuous use the mask will remain active for the 8 hours, or until the end of the operational window, even if removed and not worn.

The therapy should be repeated each night. When not in use, store Noctura 400 away from any liquids, metal objects and electronic devices.

How to Store Noctura 400

When not in use, store the Noctura 400 Pod in its Fabric Mask.

Store away from metal objects and electronic devices that use wireless networks such as e-readers, tablets, mobile phones and cordless telephones.

Store the Pod and Fabric Mask in a cool dry place away from direct sunlight.

General household dust and cotton fibres will not have an effect on the device.

Keep out of reach of pets or children as possible false activation could occur if within the operational window.

Care and Cleaning Instructions

The Fabric Mask is designed to be laundered and can be washed, SEPARATELY with the hook-and-loop touch fastener closed, in a washing machine at a maximum of 30 °C. Make sure the Pod IS REMOVED FIRST and is not re-inserted until the Fabric Mask is fully dry. Allow to dry in air, do not wring, tumble dry, iron or place on hot surfaces to accelerate drying. Do not re-use until fully dry and moisture free.

The Pod can only be wiped clean using a dry cloth or by using the Pod wipes provided. Prior to cleaning, the Pod must be fully removed from the Fabric Mask. Allow the Pod to dry fully before re-inserting into the Fabric Mask.

Return Instructions

When the operational lifetime of the Pod has expired (as indicated on the outer packaging of the Pod), clean the Pod with a Pod Wipe and place into the Return Envelope. Please ensure the Pod is returned for analysis. There is no need to return the Fabric Masks.

In the Event of a Fault or Device Failure

In the event of a fault or device failure please contact your provider.

Technical Information

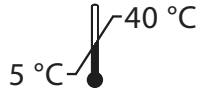
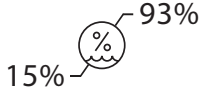
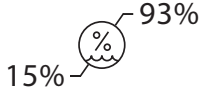
Pod

Name and address of legal manufacturer and date of manufacture	PolyPhotonix Medical Ltd., NETPark, Sedgefield, County Durham, TS21 3FG, United Kingdom. For date of manufacture see packaging.
Use by date, year and month, should not be used after end date	For use by date see packaging.
Part Number	PPX-PODASSY1 - 10058
Medical Device Classification	Class IIa
Product Colour	White
Enclosure Material	Polypropylene (Copolymer and 3% Masterbatch)
Dimensions (length x width x height in mm)	125 x 60 x 12
Weight (g)	56
Light Source	OLED (peak wavelength 502 ± 5 nm) 74 cd/m^2 x2

Power Supply	CR2450 Lithium Coin Cells x2
Power on Mechanism	Capacitive Sensor
Auto Power Off	Yes
Face Contact Detection	Yes
Usage Recording Ability	Yes
Date and Time Sensitive	Yes
Pre-defined Dosage Limitation	Yes
Light Intensity Regulation	Yes
CE Mark	CE 1639
IP Rating **IP22**	IP22 is the International Protection rating for use in the home and means it is protected against insertion of fingers and will not be damaged if it is exposed to dripping water.
	Noctura 400 has been classified as a BF applied part.
	Follow instructions for use.

	Not for general waste.
	Recycle by returning to the manufacturer.
Batch Code	For batch code see packaging.

Permissible Environmental Conditions:

	Temperature	Humidity
Operation		
Transportation & Safe Storage		 Non-condensing

There are no pressure sensitive parts in Noctura 400.

Fabric Mask

Name and address of manufacturing company	PolyPhotonix Medical Ltd., NETPark, Sedgefield, County Durham, TS21 3FG, United Kingdom.
Part Number	PPX-FabricMask- 10010
Product Colour	Black
Material Composition	Outer Fabrics: Polyamide, Elastane Non-slip Grip Strips: Thermoplastic Polyurethane Inner Foam: Polyether Polyurethane Glue: Polyurethane Hook-and-loop Touch Fastener: Polyamide and Polyester
Dimensions (length x width x height in mm)	638 x 96 x 8 (without Pod)
Weight (g)	33
CE Mark	CE 1639
	Do not bleach.
	Do not dry clean.
	Machine wash SEPARATELY at 30 °C.

	Dry flat.

Keep away from fire and flames.

Further Information

If you would like a leaflet with larger text, please contact: +44 (0) 1740 625 555.

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Version 5, 24/06/2021

EC REP

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C/ Horacio Lengo n18
C.P 29006 Málaga-Spain
info@cmcmedicaldevices.com

POLYPHOTONIX
MEDICAL

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Manufactured By:
PolyPhotonix Medical Ltd.
NETPark
Sedgefield
County Durham
TS21 3FG
United Kingdom