A new approach to the management of Diabetic Retinopathy
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Introducing Noctura 400

What is Noctura 400?

- The Noctura 400 sleep mask is an innovative technology, which can be used to prevent and treat Diabetic Retinopathy and Diabetic Macular Oedema
- Noctura 400 consists of organic light-emitting diodes (OLEDs), which are housed in a pod inside a soft cushioned fabric mask
- Designed to be worn at night, without any interference to a patient’s normal sleeping hours
- The treatment is non-invasive and programmed to administer a precise dose of low-level light through closed eyelids, as part of a continuing therapy
- The sleep mask can be used throughout all stages of Diabetic Retinopathy
- Patients keen to prevent or treat Diabetic Retinopathy and Diabetic Macular Oedema can purchase the mask now
- Treatment costs less than £3 per day (including an initial consultation and regular ongoing monitoring checks with an optometrist)
Noctura 400 breaks the cycle of Diabetic Retinopathy

How does Noctura 400 work?

- Noctura 400 combats this vicious cycle by emitting light to the eye, overnight, through closed eyelids
- The light stops the photoreceptors in the retina from ‘dark adapting’
- As dark adaptation is prevented, the oxygen requirements remain at daytime level – stopping the over production of VEGF and allowing the retina to repair itself to the best of its ability
- The colour of the light emitted has been specifically chosen as the most effective for this treatment
- The user can wear the mask for a continuous period of up to 8 hours per night, within a specified 14 hour operational window, usually 20:00 until 10:00
- A patient’s use of the mask is detected by sensors and recorded onto a chip, all contained within the mask
- At the end of a 12 week period, the mask is returned for analysis and a replacement mask is provided
- The collected usage data allows the clinician to compare the patient’s usage of the mask with changes in vision
Evidence / Efficacy

The Noctura 400 sleep mask is fully CE marked, based on proven safety and efficacy data.

Noctura 400 has demonstrated clinical repair in 66% of patients and no associated complications.\textsuperscript{1-4}

Noctura 400 has been evaluated in people with:

- Mild to moderate non-proliferative Diabetic Retinopathy\textsuperscript{1,2}
- Early, untreated and progressive Diabetic Macular Oedema\textsuperscript{2-4}
- Moderate Proliferative Diabetic Retinopathy\textsuperscript{2}

After only 3 months of treatment, patients showed a reduction in retinal thickness and intra-retinal cysts and a decrease in micro-vascular permeability and leakage\textsuperscript{2-4}

Further health economic evaluations are underway:

CLEOPATRA – Lead site Moorfields Eye Hospital, London
- Multi-centred randomised controlled single-masked trial (15 sites)
- 300 patients with non-centre involving DMO
- To evaluate if the mask can prevent progression of early DMO
- Follow up over 24 months

CANDLE – Lead site Ashford and St Peters Hospital, UK
- Multi-centred randomised controlled trial (18 sites)
- 240 patients with centre-involving DMO
- To determine reduction in number of intra-vitreal injections required when mask worn as a adjuvant therapy
- Follow up over 12 months

References
2. Data on file - 2016
4. Data on file - 2016

The Noctura 400 sleep mask is available to buy
Testimonials

John Brown  
*Middlesbrough, North Yorkshire*  
“I believe that the use of the mask has not only helped halt the retinopathy but has also been a major factor in reducing its effect”

David Coyle  
*Consett, County Durham*  
“It’s really given me hope for the future as before I started wearing the sleep mask, my eyes seemed to be deteriorating quickly”

Barbara Pariff  
*Colchester, Essex*  
“The sleep mask gave me hope at a very bad time. I had worried about losing vision and not being able to drive or even read a book. You naturally have fears about that loss of freedom”

David Stoddart  
*Barnard Castle, County Durham*  
“Diabetes ruins your life. It has already taken my legs and I don’t want it to take my eyes as well”

Neil Walker  
*Sidcup, Kent*  
“It’s terrifying to be told you have retinopathy. A million scary thoughts go through your head about losing your sight. I’m only 40 and I have children; Libby, 11, Jake, 14 and Connor, 16. I want to be able to see them grow up; to see their wedding days”

Sue Wales  
*Farnham, Surrey*  
“T’m no longer worried about losing my driving licence, no longer worried about losing my house or my job.”

Noctura 400 gives hope to the millions who are affected across the globe, that an affordable and non-invasive treatment can be provided
How to get Noctura 400

Purchase the mask for under £3 per day in 3 easy steps:

1. Call 01740 669 143 to arrange an appointment with a home-visiting optician or independent Noctura 400 supplier

2. Your eye health will be examined and you’ll be carefully assessed to see if a Noctura 400 sleep mask can benefit you

3. If Noctura 400 can benefit you, the optometrist will set up a payment plan and you’ll be supplied your first mask

- The Noctura 400 is available through approved pharmacy and optometry high street outlets
- For any help or information please contact the Noctura Advisory Line on 01740 669 143, or visit www.noctura.com

The NHS is reviewing the most appropriate clinical pathway for the adoption of Noctura 400. It's unlikely that all Diabetic Retinopathy patients would be eligible for a mask paid for by the NHS.
Diabetic Retinopathy

• According to the WHO, the number of people with diabetes has risen from 108 million in 1980 to 422 million in 2014. This figure is set to exceed 500 million before 2030

• Estimates show that over 4 million people in the UK have diabetes

• Type 1 diabetes affects over 370,000 adults in the UK

• Type 1 diabetes can develop at any age but usually appears before the age of 40, especially in childhood. It is the most common type of diabetes found in children

• Type 1 is on the rise, growing fastest in the under fives

• Type 2 diabetes affects over 3 million UK adults, while a further 1 in 3 adults could be pre-diabetic

• 280,000 people are diagnosed with Type 2 diabetes each year in the UK

• Diabetic Retinopathy is the leading cause of preventable blindness among working-age individuals in developed countries – it can develop for years without symptoms

• According to the NHS, 1280 new cases of blindness caused by Diabetic Retinopathy are reported each year in England alone

• A further 4200 people in England are thought to be at risk of vision loss through Diabetic Retinopathy

• The longer you have had diabetes, the greater your chance of developing retinopathy

• Almost all Type 1 and two thirds of Type 2 diabetes patients will develop retinopathy within 20 years of diagnosis

• The risk of developing Diabetic Retinopathy is known to increase with age as well as with poor blood sugar control and high blood pressure
What is Diabetic Retinopathy?

Diabetic Retinopathy is caused by changes to the blood vessels of the retina. Poor glucose control and hypoxia cause new weak blood vessels to grow and leak fluid into the back of the eye (the retina). Abnormal blood vessels also grow on the surface of the retina which can bleed and block vision.

Watch the video

Normal Retina

Diabetic Retina

Normal vision

Vision with Diabetic Retinopathy
Diabetic Retinopathy

Diabetic Retinopathy can develop for years without any symptoms.

**Symptoms**
- Sudden changes in vision/ blurred vision
- Eye floaters and spots
- Double vision
- Eye pain

**Common Risk Factors**
- Protein in urine
- Prolonged diabetes
- High blood pressure
- Poor blood glucose control
- Raised blood fats (triglycerides)

All diabetes patients should have regular dilated eye exams.
Diabetic Retinopathy

- Diabetic Retinopathy occurs at night during dark adaptation. As the eye adapts to the dark, more oxygen is required than during the day
- In a healthy eye there is just enough oxygen to cope with demand. In a diabetic patient, the need for extra oxygen cannot be met and their eye (retina) begins to suffer from hypoxia
- The body’s response produces a hormone known as VEGF which leads to the growth of new blood vessels. It is these changes in the blood vessels that cause Diabetic Retinopathy
- Due to high blood glucose levels, the new weak blood vessels are prone to bleed and leak fluid into the retina
- The build-up of fluid further reduces the amount of oxygen available in the retina, creating a vicious cycle, as hypoxia sets in again

Diabetic Retinopathy occurs in three different forms:

1. **Background retinopathy**
   Early stages of retinal damage – not detectable without eye examinations

2. **Proliferative retinopathy**
   New growth of weak blood vessels can lead to leaking (vitreous haemorrhages) and to scarring at the back of the eye and detachment of the retina, causing blindness

3. **Diabetic macular oedema**
   Commonly caused by fluid building up on the macula – can effect central vision

*Diabetic Retinopathy and Diabetic Macular Oedema are serious complications of diabetes, which can lead to complete loss of vision*
Current Treatments

Some of the treatments available (once retinopathy has advanced) include:

- Laser photocoagulation treatment
- Intraocular injections
- Steroid intravitreal implant

These treatments can be costly, invasive, uncomfortable, and the efficacy can fade with time. They may have side effects, including pain, temporary visual impairment and dry eyes.\(^1\)\(^-\)\(^3\)

Traditional treatments for Diabetic Retinopathy and Diabetic Macular Oedema include laser treatment, invasive intraocular injections into the eye, or steroid implants

- The current pan-retinal photocoagulation (laser treatment) or intraocular injections of anti-VEGF pharmaceutical treatments are costly to the NHS, contributing to its £10bn expenditure on diabetes.\(^4\)
- Intraocular injection treatments are invasive and uncomfortable.\(^2\)
- Laser treatment causes permanent damage to photoreceptors and does not prevent new weak vessel growth.\(^1\) Damage to photoreceptors can lead to reduced night vision
- Current treatments are only recommended at a late stage in the development of these eye complications, when a patient’s eyesight may already be threatened.\(^1\)\(^,\)\(^3\)\(^,\)\(^5\)

Most sight loss due to diabetes is preventable if treatment is given early

PolyPhotonix has developed Noctura 400 - a “Sleep Mask” for the prevention and treatment of Diabetic Retinopathy, which is a home-based, non-invasive, monitored therapy, and will be delivered at a fraction of the current treatment cost.

References
Introduction to PolyPhotonix

Based in the North East, the award-winning health technology firm PolyPhotonix is pioneering the early adoption of organic light. Working with designers and key customers, it is creating new products and supporting the design process right through to manufacture based at the National Printable Electronics Centre.

Using state of the art in-house facilities in partnership with the Centre for Process Innovation, PolyPhotonix are researching the application of light-based therapies and developing light treatment for retinal diseases.

The Noctura 400 Sleep Mask is part of a monitored ophthalmic treatment for Diabetic Retinopathy. Partnering with Fight for Sight, the UK’s main eye research charity, to share a commitment which will help create a future so everyone can see, through innovation and research.

Richard Kirk, Chief Executive Officer, has over 15 years’ experience in the field of medical research and printed electronics. Richard is well recognised as a pioneer in material science and its applications.

He is credited for many world’s first applications using inorganic and organic light emitting materials. He is a regular keynote speaker internationally and sits on a number of industrial and government advisory boards. Richard and his company have won many international and national awards for innovation, research and business.

With an early life as a successful artist based in France, Richard has a thorough understanding of the creative process and a unique view on the development of markets for innovative research.

Key People in PolyPhotonix

Richard Kirk
Chief Executive Officer

Ralph Pickles
Chairman

Kirk Siderman-Wolter
Finance Director

Martin Holland
Operations Director

Dr Alex Cole
Chief Scientific Officer
Awards

- NHS Innovation Award
- North East Business Award for Durham and Wearside 2015
- BQ North East’s Emerging Entrepreneur Award 2015
- IChemE Awards 2014
- Top 100 UK Manufacturer 2014
- RTC North award 2014
- IET Innovation Award 2014
- National Business Award 2014
- IChemE Global Award 2014
- Made in the North East Innovation Award 2014
- IChemE Award Finalist 2014
- National Business Awards Finalist 2014

Partners

LloydsPharmacy  FIGHT FOR SIGHT TheEye Research Charity  TheOutsideClinic
FAQs

Does the light make it difficult to sleep?
No, the wavelength (or colour) of the lights has been specifically chosen so that your eyes should ignore it. After a couple of minutes of exposure to the light whilst trying to sleep, the light appears to fade.

What stage of Diabetic Retinopathy do I have to have to use the mask?
People with any stage of Diabetic Retinopathy can use the mask whether or not they show signs of retinopathy. The mask is designed to reduce hypoxia in the eye which is present at some level in all diabetics.

Is it safe to use?
Yes it is perfectly safe to use. It will not upset circadian rhythm and the wavelength of light used is not at all dangerous. The level of light has been specifically chosen to cause no damage to the eye and no damage psychologically. You only need to wear the mask while sleeping.

What happens if you keep your eyes open with the mask on?
It will cause no damage as the mask works safely in the visible spectrum. It is such a low level light that you can take the mask straight off and there are no glare spots left in the eye once the mask is removed.

Is the treatment a life-long treatment?
At the moment, yes. All evidence suggests continuous treatment is the most beneficial. Taking a break from using the mask could lead to further hypoxia which is the main cause of retinopathy in diabetics. Diabetes is the underlying condition which causes diabetic retinopathy so as long as diabetes is present retinopathy has the chance to develop.

How can I purchase the mask?
The mask is available in the UK from a number of optometrists as well as The Outside Clinic, a national home-visiting optician working in partnership with Lloyds Pharmacy.

Where can I buy Noctura 400?
Noctura 400 is currently available to be purchased privately.

Should I replace laser treatment or intraocular injections with the mask?
No. At this point in time the mask should be used alongside any NHS treatments you are currently receiving.

When will it be available on the NHS?
Noctura 400 is not currently available on the NHS however PolyPhotonix are working towards this and are hoping to update soon. Please check our websites www.polyphotonix.com and www.noctura.com for latest news.
FAQs

Will it improve my eyesight?
Noctura 400 is designed as a treatment for Diabetic Retinopathy. If successful, the mask will improve the condition.

Is there a chance it could make my sight worse?
No. We’ve undergone extensive safety trials and there is no indication it will make your sight worse. You must attend your 12-weekly check-ups with your optometrists where you purchase your mask to monitor the condition of the disease.

It is a big investment – what if I don’t like it or find it uncomfortable?
The mask has undergone extensive design usability trials. Some may find it unusual for the first couple of weeks but most people adapt quickly. If you still want to cancel your subscription, please discuss this with your optician.

Will the mask get thinner?
We anticipate as it is redesigned over the next few years it will reduce in size.

I have just had my first injection, not due to diabetes but due to inflamed and bleeding blood vessels caused by a genetic condition called PXE. Can I purchase a mask?
Unfortunately not. Noctura 400 is designed as a treatment for Diabetic Retinopathy only and as such can only be sold as a treatment for this purpose.

I suffer from Age-related Macular Degeneration. Can I purchase a mask?
Unfortunately not. Noctura 400 is designed as a treatment for Diabetic Retinopathy only and as such can only be sold as a treatment for this purpose.

Can I sleep with a light on in my bedroom? / Can I just buy green curtains? / Can I just buy a green night light?
The mask has been designed with a very specific wavelength of light as the treatment for Diabetic Retinopathy. This particular wavelength also allows a person to have undisturbed sleep patterns.

When will Noctura 400 be available in the USA and Australia?
The mask is currently being rolled out across the UK. PolyPhotonix are working towards expansion of the brand across the globe.

Can I join a clinical trial?
Our clinical trials are being run completely independently to the manufacturer and as such Noctura and PolyPhotonix are unable to direct any people to the trials. The trial coordinators are responsible for recruitment into the trials and will contact people on their own records who may be appropriate as participants.
Contact Us

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