

## Noctura 400 Sleep Mask for diabetic retinopathy



### TECHNOLOGY

The Noctura 400 Sleep Mask, developed by [PolyPhotonix Ltd](#), is a non-invasive light based therapy for the treatment of patients with diabetic retinopathy (DR) or diabetic macular oedema (DMO). The sleep mask is worn over the patient's eyes at night to deliver a precise dose of light therapy as they sleep.



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The Noctura 400 sleep mask consists of two parts, a fabric mask and a light emitting 'pod' that is inserted inside the mask. The pod contains two battery-powered organic light emitting diodes that when activated, are programmed to deliver the correct dose of light during the patient's normal sleeping hours. The wavelength has been selected to be absorbed primarily by the rod photoreceptor cells in the retina, without affecting the cone photoreceptors, which would keep patients awake.

When rod cells dark adapt, they require more oxygen. However in patients with diabetes, high blood sugar levels can cause damage to blood vessels, preventing enough oxygen from reaching the retina (hypoxia). The technology works by preventing the rod cells from dark adapting, thereby reducing the oxygen demand of the retinal cells and avoiding hypoxia. This slows or stops the production of vascular endothelial growth factor (VEGF), which causes the production of new weak blood vessels in the eye that leak fluid. This results in a build-up of fluid (oedema) in patients with diabetic retinopathy, which can affect eyesight.

The Noctura 400 sleep mask is intended to be a disposable, single patient use device. It is designed to be used for up to eight continuous hours a night for a period of 12 weeks before it is replaced. The mask also records when it is being used so compliance data can be downloaded every 12 weeks by clinicians to monitor treatment effectiveness.

The company received a CE mark for the Noctura 400 sleep mask in December 2012 and it has been available privately in the UK since September 2014. The company are currently in discussions with clinical commissioning groups (CCGs), clinicians and NHS trusts regarding its availability on the NHS.

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### POTENTIAL FOR IMPACT

Diabetic retinopathy occurs when high blood sugar levels damage the blood vessels in the eye causing them to leak fluid. If fluid leaks into the macular, the most sensitive part of the retina, it can cause swelling (macular oedema) leading to some loss of vision. In more advanced stages, blood vessels supplying the retina are blocked and new unstable vessels form that are prone to bleeding, causing blurred and patchy vision. If left untreated, diabetic retinopathy can cause blindness.

Current treatment options for diabetic retinopathy include laser treatment called photocoagulation which aims to stabilise changes in the eye, intra-ocular anti-VEGF injections which aim to prevent the formation of new blood vessels in the eye, and surgery to remove the vitreous humour in front of the retina. These treatments are usually given at an advanced stage when vision is threatened.

The company claim that the Noctura 400 Sleep Mask offers a non-invasive treatment option that can be administered simply by patients in their own home. Compared to current treatment options, it can be used at an earlier stage, preventing disease progression and improving quality of life for patients and carers. This may also save NHS costs by reducing the amount of late-stage invasive treatment required in hospital. Clinicians can also compare patient usage data with eye scans to monitor effectiveness of treatment and encourage positive patient behaviour in managing their conditions.

The mask is supplied as a 12 week disposable mask costing £125. The company estimate that treatment (prescription and monitoring in a hospital outpatient setting) would cost £780 per year. They claim this is 75% and 88% cheaper than photocoagulation and intra-ocular injections respectively. This cost could be further reduced if used in a primary care setting. Treatment with Noctura 400 may also result in indirect cost savings for social care for patients with partial sight and blindness.

If proven to be effective, the Noctura 400 Sleep Mask may offer an alternative treatment option that could potentially improve patient experience by avoiding unpleasant, invasive procedures and reducing the number of follow up and treatment appointments required. The technology is predicted to have an impact on the following domains of the NHS Outcomes Framework ([www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk](http://www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk)):

Domain 2 Enhancing quality of life for people with long-term conditions;

Domain 3 Helping people to recover from episodes of ill health or following injury.

### EVIDENCE

#### PUBLISHED PAPERS AND ABSTRACTS

Czanner G, Gutu T, Harding SP *et al.* Safety and acceptability of an organic light emitting diode (OLED) sleep mask for the treatment of retinal diseases: INSIGHT study. The Association for Research in Vision and Ophthalmology 2015. Abstract 3161.

<http://www.arvo.org/webs/am2015/abstract/329.pdf>

Arden GB, Jyothi S, Hogg CH *et al.* Regression of early diabetic macular oedema is associated with prevention of dark adaptation. *Eye* 2011;25(12):1546-54.

<http://www.ncbi.nlm.nih.gov/pubmed/22020171>

### COMPLETED UNPUBLISHED STUDIES

Phase 1/2 clinical trial - prospective open label clinical trial of a phototherapeutic eye mask. The company are planning to publish the results later this year.

### ONGOING STUDIES

UK Clinical Research Network Study Portfolio. The clinical efficacy and safety of light-masks at preventing dark adaptation in the treatment of early diabetic macular oedema (CLEOPATRA). A multicentre phase III randomised controlled single-masked clinical trial.

<http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=16163>

<http://www.ncbi.nlm.nih.gov/pubmed/25417120>

ClinicalTrials.gov. Noctura 400 treatment for diabetic retinopathy (CANDLE): pilot study to demonstrate and evaluate the care pathway for NHS adoption.

<https://www.clinicaltrials.gov/ct2/show/NCT02207712>

### INFORMATION FROM

This Alert is based on information from the company and a time-limited internet search.