

Sleep Mask for Diabetic Retinopathy

An information guide



Sleep Mask for Diabetic Retinopathy

Evaluation of Noctura 400 Sleep Mask for Diabetic Retinopathy.

Why have I been asked?

You have been assessed by the Hospital eye service (HES) and classified as having Diabetic Maculopathy.

This is a form of retinopathy which can cause a gradual reduction in central vision, making it difficult to recognise people in the distance or small print. The hospital eye service is evaluating a new device which has been shown to help with this condition.

What is the device?

The device is called Noctura 400 sleep mask and works by using a specially tuned light to prevent the dark adaption of the cells in the eye at night.

This reduces the oxidative stress on the retina which is one of the underlying causes of diabetic retinopathy. The mask emits a low level, gentle light that glows through the closed eyelids and has been designed to prevent disturbances to sleep patterns.

It is hoped that regularly using the mask will reduce the need for conventional invasive interventions such as injections into the eye or laser treatment of the retina.

Is the device safe?

The Noctura 400 sleep mask has been awarded the CE mark which means it has been tested for both safety and effectiveness and is approved for use directed in the UK and other parts of Europe.

It has completed a number of clinical trials and has been available for private sale since September 2014. Noctura 400 has been used in more than 30 NHS hospitals, has over 450,000 hours of patient use and has not had any reportable mask related adverse events.

Benefits

Research to date has shown that using the mask regularly can slow down and even halt the progression of diabetic eye disease.

Diabetic Macular Oedema is a condition that occurs when diabetes causes fluid to build up on or under the macula - the central part of the retina that you use to see things clearly.

The mask has been effective in reducing the fluid build-up in the macular in 2/3rds of patients and it is hoped that patients wearing mask will require fewer eye injections or laser treatments as a result.

What will I need to do?

The mask will be used alongside conventional therapies and is not intended to replace the treatments you would normally receive.

You will need to wear the mask every night for a period of 24 weeks. Each mask lasts for 12 weeks, so you will receive a second mask (and return the first) half way through the evaluation.

You will still be seen by the eye service at the normal intervals and receive the treatments your doctor deems appropriate. At each appointment you will receive an Optical Coherence Tomography (OCT).

This is a non-invasive imaging test that uses light waves to take pictures of your retina (the light sensitive tissue lining in the back of the eye). It is used to help diagnose and provide treatment guidance for a number of eye conditions including diabetic retinopathy.

Over the 24 week period you should receive three of these checks. It is these readings which will help us to determine how effective the masks are. We will also record which additional therapies you will be prescribed (if any).

Some patients may not need any additional treatments after the 8-10 week assessment. It is very important for the purposes of the evaluation that the light masks are still worn up to the twenty four week time point.

What will happen to my information?

Polyphotonix (PP) Medical is a bio-phonotic research and development company who developed the Noctura 400 Sleep Mask. They will need to know your name and address so that the masks can be programmed and sent out to you.

PP will only use your personal data for the purpose of programming the masks and will not share it with any third parties. PP will send anonymised data of how much the mask was used to the statistician who will be analysing the evaluation data. As this information is anonymised, they will not be able to identify any individuals who participate in the evaluation.

As with the light mask, any data collected by the Hospital eye service will be anonymised prior to it being analysed which means that you cannot be individually identified by the data.

What if I change my mind?

Your participation is completely voluntary and you are free to withdraw from the evaluation at any time without giving a reason. Withdrawing from the evaluation will not affect the level of care you receive in the future.

What if I have any further questions about my involvement?

If you have any further questions about your involvement please contact the Diabetic Eye Screening Programme Admin Office on 01706 901711.

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If English is not your first language and you need help, please contact the Interpretation and Translation Service

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