NIGHTINGALE HOSPITAL
LONDON

PRESCRIPTION-ONLY NASAL SPRAY

For treatment-resistant depression

PRESCRIPTION-ONLY NASAL SPRAY

THERE ARE SOME PATIENTS WHOSE DEPRESSIVE SYMPTOMS REMAIN SEVERE, DESPITE TRYING NUMEROUS ANTIDEPRESSANT MEDICATIONS AND ENGAGING IN PSYCHOLOGICAL THERAPIES. SUCH PATIENTS ARE OFTEN DIAGNOSED WITH TREATMENT-RESISTANT DEPRESSION.

At Nightingale Hospital, we offer a choice of three distinct and highly specialised treatments for the management of treatment-resistant depression (TRD). These include **repetitive transcranial magnetic stimulation (rTMS), electroconvulsive therapy (ECT) and a new, prescription-only nasal spray.** All treatments have been proven to be clinically effective in aiding those with treatment-resistant depression.

Before receiving any of these treatments, you will have to be thoroughly assessed by a Nightingale Hospital consultant psychiatrist. The purpose of the assessment is to establish which course of treatment is the most appropriate for an individual patient.

The information in this booklet relates to this prescription-only nasal spray used for patients suffering from treatment-resistant depression.

WHAT IS THIS NASAL SPRAY?

Prescription-only nasal spray is a product that is used, in conjunction with an oral antidepressant, to treat adults with treatment-resistant depression.

Prescription-only nasal spray contains esketamine, which is a Schedule III controlled substance (CIII).

The decision to prescribe this nasal spray is determined by a consultant psychiatrist, and patients wishing to access this treatment must be under the care of a Nightingale Hospital consultant psychiatrist for the duration of treatment. Treatment can be accessed on a **day patient or inpatient basis.**

HOW IS NASAL SPRAY ADMINISTERED?

This treatment is administered in the form of a nasal spray.

Throughout each treatment session, you will be under the careful guidance and monitoring of a Nightingale Hospital nurse or health care assistant. You will be shown how to use the nasal spray device and, under supervision, you will administer the spray yourself.

Your treatment dosage will be prescribed by your consultant psychiatrist.

There are two 'phases' within this treatment cycle. Firstly, an **induction phase** where you will receive two treatments per week for four weeks. The next phase is the **maintenance phase**, where the frequency of your treatment will be reduced to once weekly or once fortnightly, depending on your individual needs.

During this time, you need to continue to take an oral antidepressant as prescribed. Your nurse will be able to answer any questions you may have during your appointments.

If you miss a treatment, your consultant psychiatrist may change your dose and treatment schedule.

IS NASAL SPRAY SAFE?

Prescription-only nasal spray has been subject to clinical trials undertaken with adults with treatment-resistant depression. It was **licensed in the UK for use in late 2019**. The nasal spray was also **licensed in the USA by the Food and Drug Administration (FDA) for use in early 2019**.

As this product contains esketamine, it has the potential to be abused and misused. Your consultant psychiatrist will take a thorough clinical history from you to establish any concerns around addiction. Individuals with a history of drug abuse or dependence are at greater risk when being prescribed this treatment.

If you are a patient in this high-risk group, your consultant psychiatrist, along with yourself, will need to carefully study the risks and benefits of this medication before deciding upon treatment.

IS NASAL SPRAY TREATMENT EFFECTIVE FOR THOSE WITH TREATMENT-RESISTANT DEPRESSION?

A clinical study was undertaken to compare the reduction of depressive symptoms in two groups of patients. One group received a combined treatment of an oral antidepressant and the nasal spray, and the other an oral antidepressant only. The patient group which received the combined treatment experienced a **reduction in their depressive symptoms in four weeks**.*

*(Popova V, Daly EJ, Trivedi M, Cooper K, Lane R, Lim P, et al. Efficacy and Safety of Flexibly Dosed Esketamine Nasal Spray Combined with a Newly Initiated Oral Antidepressant in Treatment-Resistant Depression: A Randomized Double-Blind Active-Controlled Study. (TRANSFORM-2). The Am Journal of psychiatry. 2019;176(6):428-38)

To be eligible for this treatment you must meet the following criteria:

- Be at least 18-years of age or above
- Be currently suffering from treatment-resistant depression
- Have tried at least two different types of antidepressants for at least six weeks each, both at an adequate treatment dose
- Have tried at least one type of psychological therapy
- Have a companion able to accompany you to and from all treatment appointments
- Be willing and able to send regular depression ratings by email
- Be willing and able to complete regular questionnaires online, or have someone who can help you do this if needed
- Be able to understand the nature and purpose of the treatment, its benefits and possible side effects

This nasal spray is contraindicated in patients who:

- Have aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels) or arteriovenous malformation
- Have a history of intracerebral haemorrhage
- Have hypersensitivity to esketamine, ketamine, or any of the excipients
- Are pregnant, breastfeeding, undergoing IVF or trying to conceive

If any of the above apply to you, you will be unable to receive this treatment.

You must advise your consultant psychiatrist if any of the following apply to you (or if you are unsure). If so, you *may* be deemed ineligible to receive this nasal spray treatment:

- You are under the age of 18
- You have a blood vessel disease (aneurysm) or an abnormal connection between your blood vessels (arteriovenous malformation), or a history of bleeding in the brain
- You have an allergy to esketamine, ketamine or any ingredients in Spravato®
- You have raised pressure within the skull
- You have severe high blood pressure
- You have raised pressure inside the eye (glaucoma)
- You have had a heart attack, or you've had slow or fast heartbeats causing shortness of breath, palpitations or chest discomfort, lightheadedness or fainting
- You have, or have ever had bipolar disorder, psychosis or symptoms of mania
- You have or have hyperthyroidism that has not been properly treated
- You have had lung problems causing breathing difficulty (pulmonary insufficiency), including Chronic Obstructive Pulmonary Disease (COPD)
- You have sleep apnoea and are extremely overweight
- You have severe liver problems
- You have a history of drug or medication-induced manic episodes
- You have taken any illegal drugs within the last two years, including cannabis
- You cannot abstain from alcohol for at least three days

WHAT ARE THE SIDE EFFECTS?

Like all medicines, this nasal spray can cause side effects, although not everybody experiences them. Listed below are some common side effects of this product. Please note the list of side effects below is not exhaustive, and further in-depth safety and risk information can be obtained through your consultant psychiatrist.

- Disassociation, meaning feeling disconnected from yourself, your thoughts, feelings and things around you
- Feeling dizzy
- Headaches
- Change in sense of taste
- Feeling sleepy
- Decreased feeling or sensitivity, including around the mouth area
- Spinning sensation (vertigo)
- Vomiting (throwing up)
- Nausea (feeling and wanting to be sick)

Serious side effects include: Increased risk of suicidal thoughts and behaviour, increased blood pressure, problems with thinking clearly and bladder problems. If you have any concerns about side effects before, during or after your experience with this medication, you should discuss these with your consultant psychiatrist or the health care professional with you during treatment.

WHAT YOU NEED TO KNOW

BEFORE THE APPOINTMENT

PLANNING AHEAD: HOW WILL YOU GET HOME FROM THE HOSPITAL AFTER TREATMENT?

Due to the potential for residual effects of treatment, patients are not to drive home afterwards. Similarly, in the interests of safety, patients will be unable to travel home unaccompanied on public transport such as tubes, trains and buses.

Therefore, it is regarded as 'best practice' for patients to be collected from the hospital and accompanied home by a companion after treatment. We realise that it may be difficult for some patients to arrange a companion for every treatment session. If this is the case, the health care professional delivering the treatment will assess each patient's suitability for leaving the hospital alone. If a patient does not have a companion to accompany them home, we recommend they book a taxi or similar service for their journey.

Apps such as Uber will allow patients to automatically set their home address as a saved destination. However, we strongly advise that patients decide to be collected after the first two or three treatment sessions; whilst they get used to the treatment and any subsequent after-effects, as these vary from person to person.

CAN I EAT OR DRINK ANYTHING?

Some patients receiving this treatment may experience nausea or vomiting. Because of this, you should avoid eating for two hours and avoid drinking liquids for 30 minutes before treatment.

IF YOU USE STEROIDS OR DECONGESTANT MEDICINES

If you use steroid or decongestant nasal sprays, avoid using them for one hour before your treatment.

DURING THE APPOINTMENT

The hospital has a dedicated nasal spray treatment room. At the start of your appointment, the nurse will talk you through the steps of the treatment session.Before treatment commences, you will have various physical observations taken, including your blood pressure and pulse measured.

After you self-administer the nasal spray, there will be a period of close observation for two hours. During this time, you will be asked to rest comfortably in the treatment room.

A nurse will be present throughout and will continue to regularly monitor you physically, and check for any possible side effects.

You will be able to leave the hospital when the nurse determines it is safe for you to do so. At this point, your companion will need to escort you home safely.

AFTER THE APPOINTMENT

You may feel tired and have a headache. You are advised to rest for the remainder of the day. If you have a headache it is safe to take an over-the-counter medicine such as paracetamol.

Because of possible side effects affecting mental alertness and motor coordination, you will not be able to drive, operate machinery or do anything which requires you to be completely alert, until the following day, after a night's sleep.

You will be given a contact number and email address of the nurses in charge of the treatment service, should you want to discuss any concerns or possible side effects.

WHY CHOOSE NIGHTINGALE HOSPITAL FOR NASAL SPRAY FOR TREATMENT-RESISTANT DEPRESSION?

- Our treatment service is led by renowned UK consultant psychiatrist, Dr Christopher Muller-Pollard
- Nightingale Hospital has many years of experience in delivering innovative, effective and safe specialised treatments for treatment-resistant depression
- We were the first private hospital in the UK to introduce repetitive **transcranial magnetic stimulation (rTMS)**, and have a long partnership with the NHS to deliver **electroconvulsive therapy (ECT)**
- We are the first and only private hospital to offer nasal spray treatment for patients with treatment-resistant depression
- A hospital setting means we have access to a full medical team on site
- We have devised extensive treatment protocols, to provide maximum patient safety, and all staff involved in the service have received comprehensive training
- We have a dedicated treatment room, designed specifically for patients receiving this nasal spray

REFERRAL INFORMATION

Individuals can self-refer themselves to Nightingale Hospital for nasal spray treatment. Additionally, GPs and other health professionals can refer patients. Patients need to be under the care of a Nightingale Hospital consultant psychiatrist for the duration of treatment.

BILLING AND PAYMENT

The treatment includes an induction phase lasting 4 weeks, consisting of 8 sessions, with the cost breakdown provided below for different age groups. After the induction phase, each session is priced at £1,125 per session, regardless of age. The total number of sessions will be determined by your consultant's review and your response to the treatment.

The billing breakdown for treatment is illustrated below.

PAYMENT SCHEDULE		
	INDUCTION PHASE - 4 WEEKS/8 SESSIONS	POST INDUCTION PHASE - COST PER SESSION
UNDER 65 YRS	£10,000	£1,125 / PER SESSION
OVER 65 YRS	£7,500	£1,125 / PER SESSION

The first month of treatment, also known as the 'induction phase', involves the highest frequency of appointments and treatment dosages. The cost of the induction phase also **includes** a follow-up appointment with the consultant psychiatrist responsible for your referral for treatment. With the exception of this one follow-up appointment, **the costs of any subsequent appointments with your consultant psychiatrist will be billed directly to you, by your treating consultant.**

At the start of each stage of treatment, i.e., at the beginning of each monthly treatment cycle, patients are required to pay the full monthly amount in advance. This can be taken over the phone by contacting our Patient Services Team using the contact details at the end of this leaflet.

The nasal spray contains a controlled substance. The hospital purchases the medication monthly in advance, per each treatment cycle, on a **named patient** basis.

As the supply is specifically for a named patient, it means that in no circumstances can the supply be transferred to another. Therefore, if for any reason you do not want to proceed with treatment, any fees you have paid in advance are **strictly non-refundable**.

Some private medical insurers have been known to fund this treatment on a case-by-case basis. We suggest contacting your insurer to find out further details regarding potential funding.

Nasal spray for treatment-resistant depression can be provided at Nightingale Hospital from **Monday to Friday from 9:00am – 5:00pm**.

NIGHTINGALE HOSPITAL

11-19 Lisson Grove
Marylebone, London
NW1 6SH

nightingalehospital.co.uk

REFERRALS INFORMATION

For all enquiries regarding admission and referrals, the **Patient Services Team** can be contacted by telephone between the hours of 8:30am - 5:00pm.

Telephone: +44 (0)20 7535 7732
Fax: +44 (0)20 7724 5976
Email: patientservices@nightingalehospital.co.uk

You can also contact our **Treatment-Resistant Depression Team** directly during business hours.

Telephone: +44 (0)20 7535 7931
Email: esketamine@nightingalehospital.co.uk

Outside of these hours, the **hospital reception** can be contacted 24 hours a day, 7 days a week.

Telephone: +44 (0)20 7535 7700