

SPRAVATO® NASAL SPRAY

Esketamine Hydrochloride (28mg)

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What SPRAVATO® is used for

SPRAVATO® is used in adults to reduce the symptoms of depression, such as, feeling sad, anxious, or worthless, sleeping difficulties, change in appetite, loss of interest in favourite activities, feeling of being slowed down. It is given, together with another antidepressant, if you have tried at least 2 other antidepressant medicines but they have not helped.

SPRAVATO® is used with an oral antidepressant, for the treatment of depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior.

How SPRAVATO® works

SPRAVATO® contains the active substance esketamine. This belongs to a group of medicines called anti-depressants and you have been given this medicine to treat your depression

Before you use SPRAVATO®

- When you must not use it

- Do not use SPRAVATO®
- if you are allergic to esketamine, a similar medicine called ketamine used for anaesthesia, or any of the other ingredients of this medicine
 - if you have ever had certain conditions such as:
 - an aneurysm (a weak spot in a blood vessel wall where it widens or bulges out)
 - bleeding in the brain
 - if you recently had a heart attack (within 6 weeks)

This is because SPRAVATO® can cause a temporary increase in blood pressure that may lead to serious complications in these conditions.

Do not use SPRAVATO® if any of the above apply to you. If you are not sure, talk to your doctor before using SPRAVATO® - your doctor will decide whether or not you can use this medicine.

Elderly (>65 years)

If you are elderly (>65 years), you will be carefully monitored as you may be at increased risk of falling when you start moving around after treatment.

Children and adolescents

Do not give this medicine to children and adolescents younger than 18 years of age. This is because SPRAVATO® has not been studied for treatment-resistant depression in this age group.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Contraception

If you are able to become pregnant you must use contraception during treatment. Talk with your doctor about suitable methods of contraception.

Pregnancy

Do not use SPRAVATO® if you are pregnant.

If you become pregnant while being treated with SPRAVATO®, talk to your doctor straight away – to decide whether to stop treatment and to learn about other options for treatment.

Breast-feeding

Do not use SPRAVATO® if you are breast-feeding. Talk to your doctor before using SPRAVATO® if you are breast-feeding. Your doctor will discuss with you whether to stop breast-feeding or stop using this medicine. Your doctor will take into account the benefit of breast-feeding for you and your child, and the benefit of treatment for you.

- Before you start to use it

Talk to your doctor before using SPRAVATO® if you have:

- a heart problem which is not well controlled such as: poor blood flow

in the blood vessels of the heart frequently with chest pain (such as angina), high blood pressure, heart valve disease or heart failure

- ever had problems with the blood supply to your brain (such as a stroke)
- ever had problems with drug abuse – prescribed medicines or illegal drugs or a problem with alcohol
- ever had a condition called psychosis where you believe in things that are not true (delusions) or see, feel, or hear things that are not there (hallucinations)
- ever had a condition called bipolar disorder, or symptoms of mania (where you become very overactive or over excited)
- ever had an overactive thyroid that is not properly treated (hyperthyroidism)
- ever had lung problems causing breathing difficulty (pulmonary insufficiency), including Chronic Obstructive Pulmonary Disease (COPD)
- sleep apnoea and are extremely overweight
- ever had slow or fast heartbeats causing shortness of breath, palpitations or chest discomfort, feeling lightheaded or fainting
- had a serious head injury or serious problems affecting the brain, particularly where there is increased pressure in the brain
- severe liver problems.

If any of the above apply to you (or you are not sure), talk to your doctor before using SPRAVATO®. Your doctor will decide whether you should use this medicine.

Depression getting worse

Tell your doctor or go to the nearest hospital straight away if you have thoughts of harming or killing yourself at any time.

You may find it helpful to talk to a relative or a close friend if you are depressed and ask them if they think your depression is getting worse or if they are worried about your behaviour. You might ask them to read this leaflet.

Blood pressure

SPRAVATO® can increase your blood pressure for about 1 to 2 hours after you use it so your blood pressure will be measured before you start using SPRAVATO® and after using it.

If your blood pressure is high before using this medicine, your doctor will decide whether to start the medicine or wait until your blood pressure is lower. If your blood pressure goes up after using this medicine and stays high for more than a few hours, you may need to have some more tests.

This medicine may cause a temporary increase in your blood pressure after taking a dose. Your blood pressure will be checked before and after using this medicine. Tell the medical staff right away if you get chest pain, shortness of breath, sudden severe headache, change in vision, or seizures (fits) after using this medicine.

- Taking other medicines

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Using SPRAVATO® with certain medicines may cause side effects. Especially tell your doctor if you take:

- Medicines used to treat nervous disorders or severe pain (for example, benzodiazepines, opioids)
- Stimulants such as those used for conditions such as narcolepsy or medicines for ADHD (for example, amphetamines, methylphenidate, modafinil, armodafinil)
- Medicines that can increase your blood pressure, such as, thyroid hormones, asthma medicines such as xanthine derivatives, medicines for childbirth bleeding (ergometrine) and heart medicine such as vasopressin.
- Medicines for depression or Parkinson's disease known as monoamine oxidase inhibitors (MAOIs) (for example, tranylcypromine, selegiline, phenelzine).

How to use SPRAVATO®

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

You will use the SPRAVATO® nasal spray yourself - under the supervision of your doctor or other healthcare professional in a healthcare setting, such as, the doctor's office or clinic.

Your doctor or other healthcare professional will show you how to use the nasal spray device

- How much to use

Your doctor will decide if you need 1, 2 or 3 nasal spray devices and how often you should go to the doctor's office or clinic for the medicine.

- When to use it

One nasal spray device delivers two sprays (one spray per nostril).

SPRAVATO® is usually used twice a week for the first 4 weeks. After the first 4 weeks, SPRAVATO® is usually used once a week. After this, SPRAVATO® is usually used either once a week or once every 2 weeks.

- How long to use it

During and after each use of this medicine, your doctor will check you and decide how long to monitor you.

- If you forget to use it

It is important to make sure you come in for your scheduled appointments, so that this medicine is effective for you.

If you have any further questions on the use of this medicine, ask your doctor.

- If you use too much (overdose)

You will use this medicine under the supervision of your doctor in the doctor's office or clinic. Therefore, it is unlikely that you will use too much.

If you use too much SPRAVATO®, you are more likely to get side effects.

While you are using it

- Things you must do

Tell your doctor if you get any of the below while you are using SPRAVATO®.

- difficulty with your attention, judgment and thinking during and after each use of this medicine, your doctor will check your condition and decide how long to monitor you.
- sleepiness (sedation), fainting, dizziness, spinning sensation, anxiety, or feeling disconnected from yourself, your thoughts, feelings, space and time (dissociation), difficulties in breathing (respiratory depression). Tell the medical staff right away if you feel like you cannot stay awake or if you feel like you are going to pass out.
- pain when urinating or seeing blood in your urine – these could be signs of bladder problems. These can occur with high doses of a similar medicine (called ketamine) used over a long period.

Tell your doctor if you get any of the above while you are taking SPRAVATO®.

- Things you must not do

SPRAVATO® with food, drink and alcohol

Some patients using SPRAVATO® may experience nausea or vomiting. You should avoid eating for 2 hours before treatment and not drinking liquids for 30 minutes before using this medicine. Tell your doctor if you take medicines or beverages containing alcohol.

Nasal sprays

If you need steroid or decongestant medicines as a nasal spray, avoid using them during the hour before your SPRAVATO® treatment.

- Things to be careful of

Driving and using machines

SPRAVATO® can make you feel sleepy, dizzy, and have other side effects that can temporarily affect your ability to drive vehicles or use machines and do activities that need you to be completely alert. After being treated with this medicine, do not take part in these activities until the next day following a restful sleep.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor if you notice any of the following side effects.

Very common (may affect more than 1 in 10 people)

- feeling disconnected from yourself, your thoughts, feelings and things around you
- feeling dizzy
- headache
- feeling sleepy
- change in sense of taste
- decreased feeling or sensitivity, including around the mouth area
- spinning sensation (“vertigo”)
- vomiting
- nausea
- increased blood pressure

Common (may affect up to 1 in 10 people)

- feeling anxious
- feeling extremely happy (“euphoria”)
- feeling confused
- feeling detached from reality
- feeling irritable
- seeing, feeling, hearing or smelling things that are not there (hallucinations)
- feeling agitated
- eyes, ears, or sense of touch are deceived or tricked in some way (something is not what it seems to be)
- panic attacks
- change in perception of time
- unusual feeling in the mouth (such as tingling or a crawling feeling)
- muscle tremors
- problems with thinking
- feeling very sleepy with low energy
- difficulty speaking
- difficulty concentrating
- blurred vision
- persistent ringing in the ears (tinnitus)
- increased sensitivity to noise or sounds
- fast heartbeat
- high blood pressure
- nasal discomfort
- irritated throat
- sore throat
- nasal dryness including dry crusts in the nose
- itchy nose

- decreased feeling or sensitivity in the mouth
- dry mouth
- excessive sweating
- frequent need to pass urine
- pain when passing urine
- urgent need to pass urine
- feeling abnormal
- feeling drunk
- feeling weak
- crying
- feeling of body temperature change

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vacines (AEFI)].

Storage and disposal of SPRAVATO®

- Storage
Do not store above 30°C.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the label. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

- Disposal
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

Product description

- What it looks like
SPRAVATO® is a nasal spray solution. This medicine is a clear, colourless solution, provided in a single use nasal spray device.

SPRAVATO® is available in pack sizes containing 1, 2, 3, or 6 nasal spray devices.

Each nasal spray device is individually packaged in a sealed blister.

Not all pack sizes may be marketed.

- Ingredients

Active Ingredient
Esketamine hydrochloride

Inactive Ingredients

Citric acid monohydrate, edetate disodium, sodium hydroxide, water for injection

- MAL number

MAL21036003ACZ

Manufacturer

Renaissance Lakewood LLC
1200 Paco Way,
Lakewood, New Jersey (NJ),
08701, United States (USA).

Product registration holder

Johnson & Johnson Sdn Bhd (3718-D)
Level 8, The Pinnacle,
Persiaran Lagoon, Bandar Sunway,
46150, Petaling Jaya, Selangor, Malaysia

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