

Package leaflet: Information for the patient

Spravato® 28 mg nasal spray, solution esketamine

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Spravato is and what it is used for
2. What you need to know before you use Spravato
3. How to use Spravato
4. Possible side effects
5. How to store Spravato
6. Contents of the pack and other information

1. What Spravato is and what it is used for

What Spravato is

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.

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 also used in adults to rapidly reduce symptoms of depression in a situation requiring immediate treatment (also known as a psychiatric emergency).

2. What you need to know before you use Spravato

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 (listed in section 6).
- 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.

Warnings and precautions

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
- 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 over-active 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 light-headed 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.

Tell your doctor if you get any of the below while you are using Spravato

- difficulty with your attention, judgment and thinking (see also “Driving and using machines” and “Possible side effects”). 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.

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.

Other medicines and Spravato

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 child birth 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).

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.

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.

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.

3. 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 (see also Instructions for use).

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.

- One nasal spray device delivers two sprays (one spray per nostril)
- Spravato is used twice a week for the first 4 weeks

If your treatment is continued:

- Spravato is usually used once a week for the following 4 weeks
- After this, Spravato is usually used either once a week or once every 2 weeks

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

Nasal sprays

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

If you use more Spravato than you should

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 (see "Possible side effects").

If you stop using Spravato

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.

4. Possible 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

Uncommon (may affect up to 1 in 100 people)

- thoughts, speech and physical movements slow down
- emotional distress
- feeling uneasy or tense
- fast eye movements that you cannot control
- being hyperactive
- increased saliva
- cold sweats
- problems walking
- low blood pressure
- **slow heart rate**

Rare (may affect up to 1 in 1,000 people)

- difficulties in breathing (respiratory depression)
- **seizure**

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. This includes any possible side effects not listed in this leaflet. The Egyptian Pharmaceutical Vigilance Center (EPVC): 21 Abd Elaziz Al Souad st. – Manial El-Rouda-Cairo, PO Box: 11451.

Website/ www.epvc.gov.eg , E-Mail/ pv.followup@edaegypt.gov.eg,

Telephones/ +2 02 25354100 _ +2 02 23640368 _ +2 02 23684381

Extention (Tel)/1303

Fax/+2 02 23684194

Extension (Fax)/1300

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Spravato

Keep this medicine 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.

Do not store above 30C.

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.

6. Contents of the pack and other information

What Spravato contains

The active substance is esketamine.

Each nasal spray device delivers 32.3mg esketamine hydrochloride equivalent to 28 mg esketamine.

The other ingredients are:

Citric acid monohydrate

Disodium edetate

Sodium hydroxide (for pH adjustment)

Water for injections

What Spravato looks like and contents of the pack

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 and as a multipack containing 24 (8 packs of 3) nasal spray devices.

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

Not all pack sizes may be marketed.

To contact us, go to www.janssen.com/contact-us

Marketing Authorisation Holder

Janssen-Cilag International NV Turnhoutseweg, 30, Beerse, B-2340, Belgium

Manufacturer

Renaissance Lakewood LLC, 1200 Paco Way, Lakewood, NJ 08701 United State of America

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THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children

Council of Arab Health Ministers, Union of Arab Pharmacists

The following information is intended for healthcare professionals only:

**Instructions for Use
SPRAVATO
(esketamine)
Nasal Spray Device**



28 mg per device

Each nasal spray device delivers
28 mg esketamine as two sprays.

Important

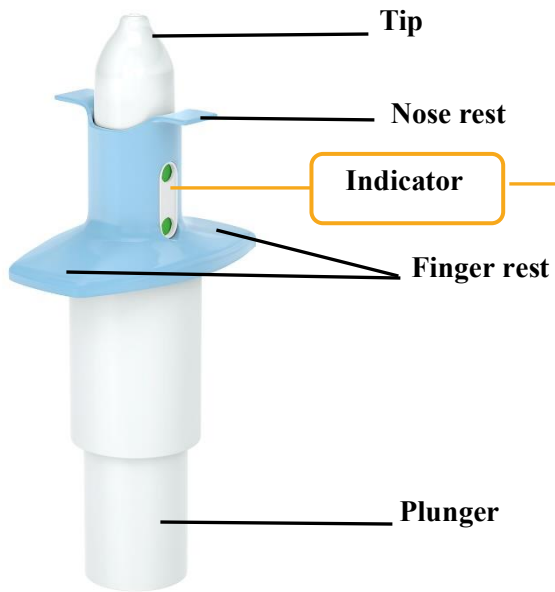
This device is intended for administration by the patient, **under supervision of a healthcare professional**. Read these Instructions for Use in full before training and supervising patient.



Need help?

For additional assistance or to share your feedback refer to the Package Leaflet for the contact information of the local representative of the Marketing Authorisation Holder.

Nasal Spray Device

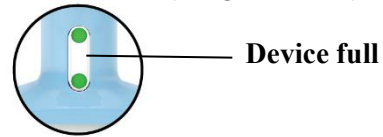


Each nasal spray device delivers 28 mg esketamine as two sprays.

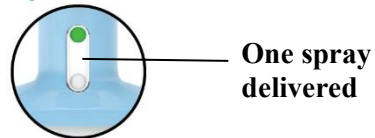
Indicator

One device contains 2 sprays
(1 spray for each nostril)

2 green dots (0 mg delivered)

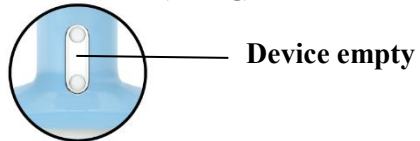


1 green dot



No green dots

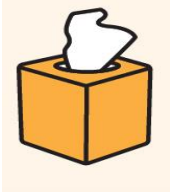
Two sprays (28 mg) delivered



Step 1

Get ready

Before first device only:



Instruct patient to blow nose **before first device only**.



Confirm required number of devices.

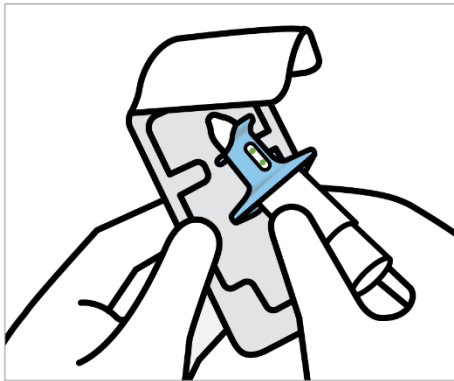
28 mg = 1 device

56 mg = 2 devices

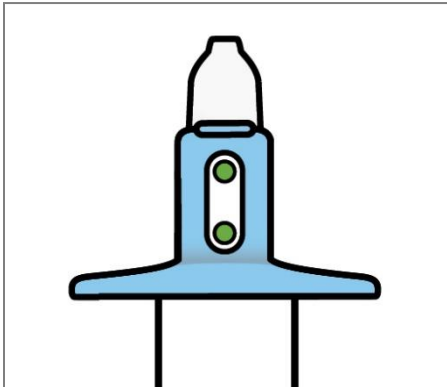
84 mg = 3 devices

Step 2

Prepare device

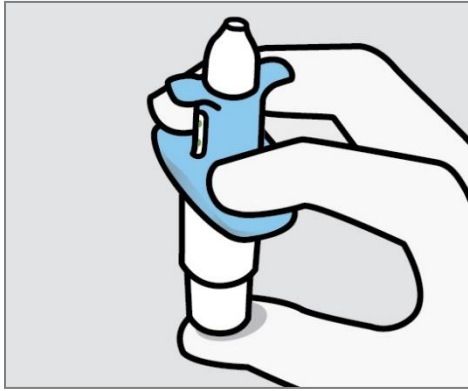


- Check expiration date ('EXP'). If expired, get a new device.
- Peel blister and remove device.



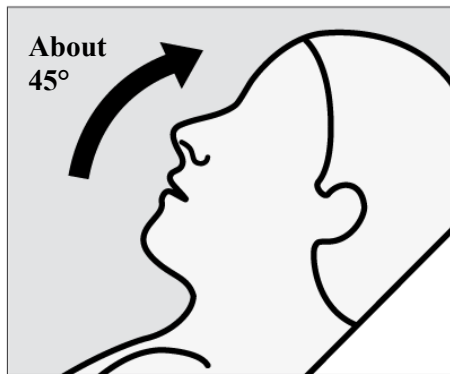
- **Do not prime device.** This will result in a loss of medicine.
- Check that indicator shows **2 green dots**. If not, dispose of device and get a new one.
- Hand device to patient.

Step 3 Prepare patient



Instruct the patient to:

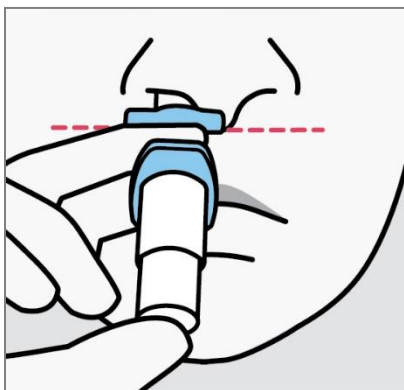
- Hold device as shown with the thumb gently supporting the plunger.
- **Do not** press the plunger.



Instruct the patient to:

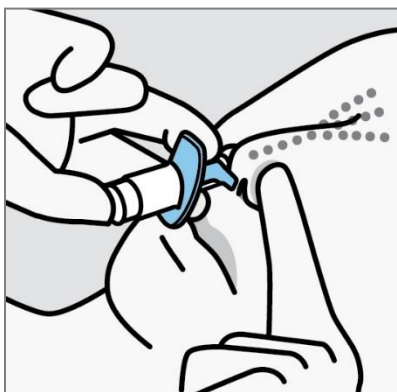
- Recline head at about **45 degrees** during administration to keep medicine inside the nose.

Step 4 Patient sprays once into each nostril



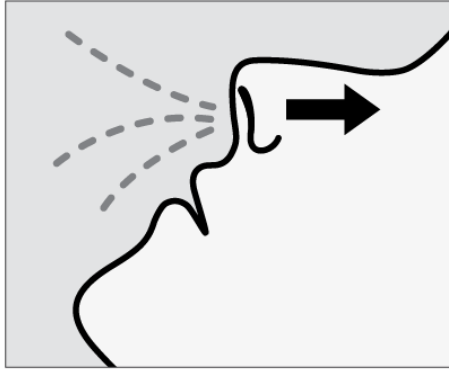
Instruct the patient to:

- Insert tip straight into the **first nostril**.
- Nose rest should touch the **skin between the nostrils**.



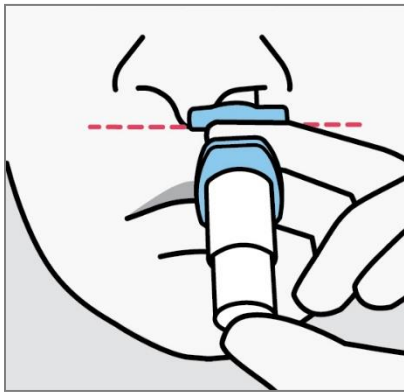
Instruct the patient to:

- Close opposite nostril.
- **Breathe in through nose** while pushing plunger all the way up until it stops.



Instruct the patient to:

- **Sniff gently** after spraying to keep medicine inside nose.

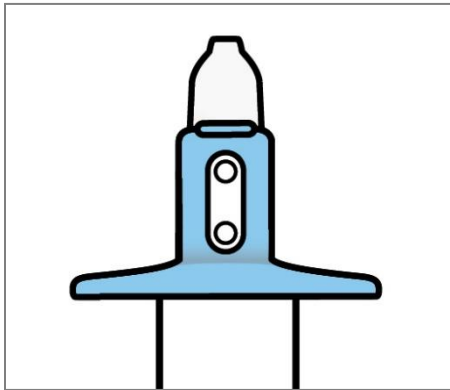


Instruct the patient to:

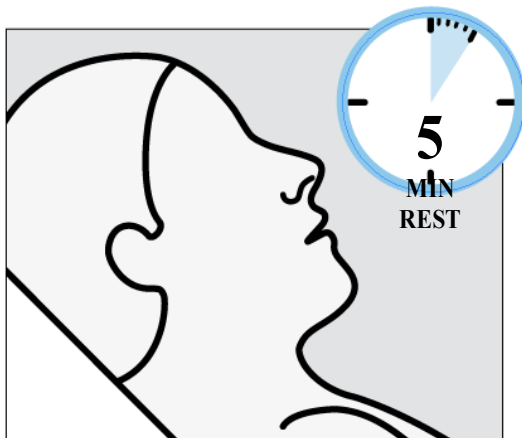
- Switch hands to insert **tip** into the **second nostril**.
- Repeat Step 4 to deliver second spray.

Step 5

Confirm delivery and rest



- Take device from patient.
- Check that indicator shows **no green dots**. If you see a green dot, have patient spray again into the second nostril.
- Check indicator again to confirm device is empty.



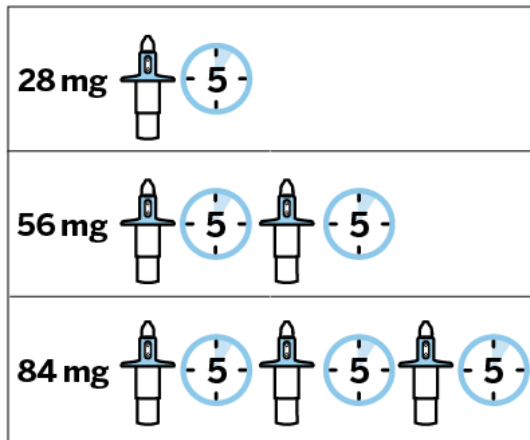
Instruct the patient to:

- Rest in a comfortable position (preferably, semi-reclined) for **5 minutes after each device**.
- If liquid drips out, dab nose with a tissue.



Do not blow nose.

Next device (if required)



- Repeat Steps 2-5 if more than one device is required.

IMPORTANT: Ensure that patient **waits 5 minutes after each device** to allow medicine to absorb.

Disposal

Dispose of used device(s) in accordance with local requirements.