

▼ This medicine is subject to additional monitoring in Australia. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

SPRAVATO®

Esketamine hydrochloride

Consumer Medicine Information

WARNING: Your healthcare professional will monitor you before and after SPRAVATO treatment and will let you know when you can go home. They will check that your blood pressure doesn't go too high, how sleepy you may feel, and if you are feeling disconnected from yourself, your thoughts, feelings and/or things around you. If you are feeling concerned about how sleepy or disconnected you feel after treatment, talk to your healthcare professional immediately.

SPRAVATO will be provided by your healthcare professional for you to use at the clinic or hospital under their direct supervision. SPRAVATO cannot be taken away from the clinic or hospital. You should not drive or operate machinery until the next day after a restful night's sleep.

What is in this leaflet

This leaflet answers some common questions about SPRAVATO. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking SPRAVATO against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor.

Keep this leaflet.

You may need to read it again.

What SPRAVATO is used for

SPRAVATO contains the active substance esketamine. This belongs to a group of medicines called

antidepressants and is used to treat depression in adults.

SPRAVATO is a nasal spray used to reduce the broad range of symptoms of depression. This medicine can help improve the symptoms of your disease and reduce the chance of your symptoms coming back.

SPRAVATO is used in people who have tried other antidepressant medicines but have not benefitted from them.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

Before you use SPRAVATO

When you must not take it

Do not take SPRAVATO if you have an allergy to:

- any medicine containing esketamine or ketamine
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take SPRAVATO if you have, or have had, any of the following medical conditions:

- an aneurysm, this is a weak spot in a blood vessel wall where it widens or bulges out.
- bleeding in the brain.

This is because SPRAVATO can cause a temporary increase in blood pressure and in both these conditions, an increase in blood pressure can cause a serious medical condition.

Do not use SPRAVATO if you are pregnant.

If you are pregnant, think you may be pregnant or are planning to have a baby, tell your doctor before using this medicine. Tell your doctor if you are trying to make your partner pregnant.

Using SPRAVATO during pregnancy has not been studied and it is not known if SPRAVATO will harm your unborn baby.

If you are able to become pregnant you must use highly effective contraception during treatment - and up to 6-weeks after the end of treatment. Talk with your doctor about methods of contraception to use.

Do not use SPRAVATO if you are breast-feeding.

The active ingredient in SPRAVATO may pass into breast milk and there is a possibility that your baby may be affected.

Your doctor will only prescribe SPRAVATO for your self-administration based on its indicated usage.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, your doctor or other health care professional will arrange for its disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, or preservatives.

Tell your doctor if you have or have had any of the following medical conditions:

- heart problems which are 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, a recent heart attack,

heart valve disease or heart failure

- slow or fast heartbeats causing shortness of breath, palpitations or chest discomfort, feeling light-headed or fainting
- problems with the blood supply to your brain (such as a stroke)
- a head injury or serious problems affecting the brain, particularly where there is increased pressure in the brain
- problems with drug abuse – prescribed or illegal drugs - or a problem with alcohol
- 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)
- you have ever had a condition called “bipolar disorder” or symptoms of mania – where you are being very over-active or over excited
- an overactive thyroid that is not properly treated (hyperthyroidism)
- lung problems causing breathing difficulty (pulmonary insufficiency)
- 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.

Tell your doctor if you are of Japanese or Chinese ancestry.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and SPRAVATO may interfere with each other. These include:

- other nasal sprays. Do not use any other nasal spray within 1 hour of using SPRAVATO.
- Central Nervous System (CNS) depressants (for example, benzodiazepines, opioids, medicines or beverages containing alcohol)
- Psychostimulants (for example, amphetamines, methylphenidate, modafinil, armodafinil)
- Monoamine oxidase inhibitors (MAOIs) medicines (for example, tranylcypromine, selegiline, phenelzine)

Some medicines may be affected by SPRAVATO or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor will have more information on medicines to be careful with or avoid while taking SPRAVATO.

How to take SPRAVATO

You will use the SPRAVATO nasal spray yourself - under the supervision of your doctor or other health care professional in the doctor's office, clinic or hospital.

SPRAVATO is used together with another antidepressant.

Follow all directions given to you by your doctor or other health care professional carefully.

Your doctor or other health care professional will show you how to use the nasal spray device and you must also read the Instructions for Use leaflet provided in the SPRAVATO pack.

If you do not understand the instructions in the Instructions for Use leaflet, ask your doctor or other health care professional for help.

How much to take

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

Your doctor will decide how many nasal spray devices and how often you should come to the doctor's office or clinic for the medicine.

- SPRAVATO is taken twice a week for the first 4 weeks.
- For some patients, after the first 4 weeks, SPRAVATO is usually taken once a week for a further 4 weeks.
- For some patients, after this, SPRAVATO is usually taken either once a week or once every 2 weeks.

During and after each use of this medicine, you will be checked, and your doctor or other health care professional will decide how long to monitor you.

- This medicine may cause a temporary increase in your blood pressure after taking a dose. Your blood pressure will be checked before and after taking this medicine. Tell the medical staff right away if you get chest pain, shortness of breath, sudden severe headache, change in vision, or seizures after taking this medicine.
- This medicine may cause sleepiness (sedation), fainting, dizziness, spinning sensation, anxiety, or feeling disconnected from yourself, your thoughts, feelings, space and time (dissociation), difficulty 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.

How to take it

Step 1.

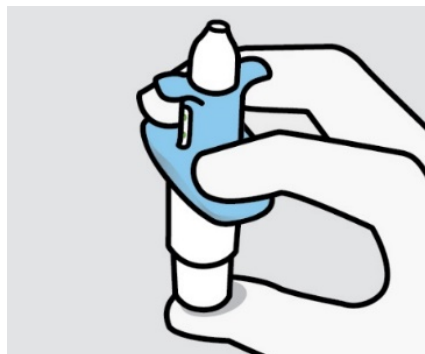
Your doctor or other health care professional will instruct you to blow your nose before using the first device only.

Step 2.

Your doctor or other health care professional will check the expiry date and remove the device from its blister and check that the indicator shows 2 green dots. They will then hand you the device.

DO NOT PRIME THE DEVICE

Step 3.

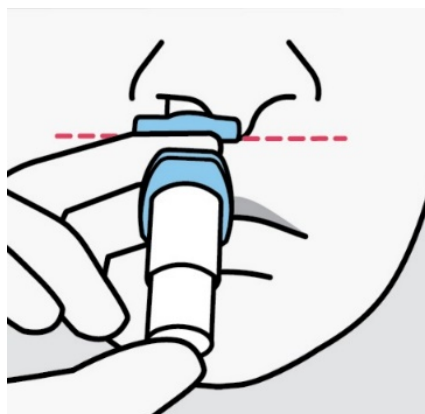


Hold device as shown with the thumb gently supporting the plunger. Do not press the plunger.

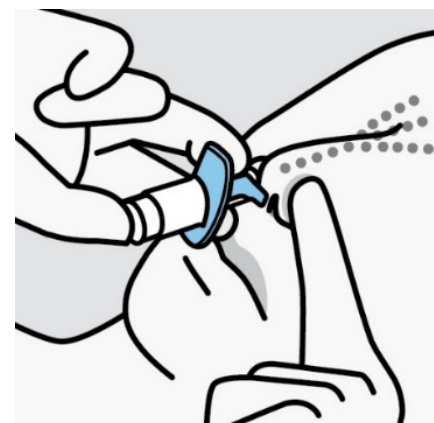


Recline head at about 45 degrees during administration to keep medication inside the nose.

Step 4.

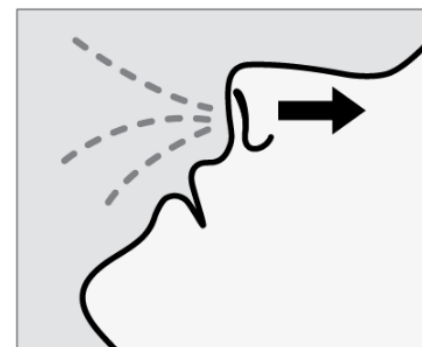


Insert tip straight into the first nostril. The nose rest should touch the skin between the nostrils.

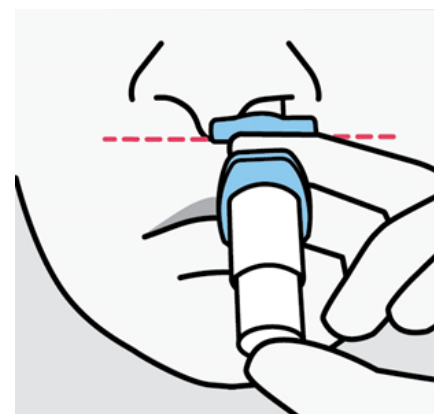


Close opposite nostril.

Breathe in through nose while pushing plunger all the way up until it stops.



Sniff gently after spraying to keep medication inside nose.



Switch hands to insert tip into the second nostril.

Repeat Step 4 to deliver second spray.

While you are using SPRAVATO

Things you must do

Be sure to keep all your doctor's appointments so your progress can be checked.

It is important to have your follow-up doses of SPRAVATO at the appropriate times to get the best effects from your treatment.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking SPRAVATO.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

If you become pregnant or your partner becomes pregnant while taking this medicine, tell your doctor immediately.

Things to be careful of

Do not drive or operate machinery after taking SPRAVATO.

SPRAVATO can make you feel sleepy, dizzy, and have other side effects that can temporarily affect your ability to drive motor vehicles or use other machines and do anything where you need 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.

If you think your depression getting worse.

Tell your doctor or go to the nearest hospital straight away if you have suicidal thoughts or thoughts of harming yourself at any time. You may find it helpful to talk to a relative or 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.

When to take it

You will be directed to use SPRAVATO by your doctor in the doctor's office or clinic.

Some patients taking SPRAVATO may experience nausea or vomiting.

You should avoid eating 2 hours before and drinking liquids 30 minutes before using this medicine.

If you need steroid or decongestant medicines as a nasal spray, avoid using these medicines within 1 hour before your SPRAVATO treatment.

How long to take it

Continue using SPRAVATO for as long as your doctor tells you.

If you forget your appointment

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

If you miss an appointment it is important that you contact your doctor as soon as possible to make a new appointment.

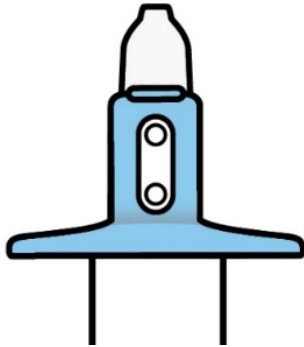
If you take too much (overdose)

This medicine will be given to you under the supervision of your doctor in the doctor's office or clinic. Therefore, it is unlikely that you will be given too much.

However, if you experience any side effects after using SPRAVATO, tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital.

You may need urgent medical attention.

Step 5



Your doctor or other health care professional will take the used device and check that the indicator shows no green dots. If there is a green dot they will have you spray again into the second nostril.



You will then rest in a semi-reclined position for 5 minutes after each device.

DO NOT BLOW NOSE.

If any liquid runs out, dab nose with a tissue.

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

It is important that you rest for 5 minutes after each device to allow the medication to absorb.

Blood Pressure

SPRAVATO can increase your blood pressure for a short time (about 1 to 2 hours) – so you will have your blood pressure measured at various times. Your blood pressure will be measured before you start using SPRAVATO and after taking 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 increases significantly after using this medicine and remains elevated for more than a few hours after dosing, your doctor may send you to another doctor for evaluation.

Side effects

Like all medicines, SPRAVATO can cause side effects although not everybody gets them. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- feeling disconnected from yourself, your thoughts, feelings and things around you
- feeling anxious
- feeling confused
- difficulty in paying attention
- change in sense of taste
- feeling dizzy
- feeling sleepy
- decreased feeling or sensitivity, including around the mouth area
- headache
- spinning sensation (“vertigo”)

- vomiting
- nausea
- increased blood pressure
- emotional distress, crying
- feeling extremely happy (euphoria)
- feeling unhappy or uneasy (dysphoria)
- problems with thinking
- muscle tremors
- difficulty speaking
- fast heartbeat
- nasal discomfort
- throat irritation or pain
- dry mouth
- excessive sweating, cold sweat
- pain when passing urine
- frequent need to pass urine
- feeling abnormal
- feeling drunk
- feeling weak with low energy (asthenia)
- problems walking
- fast eye movements that you cannot control
- making movements without purpose (psychomotor hyperactivity)
- increased saliva
- low blood pressure
- difficulty breathing (respiratory depression)

The above list includes some side effects of your medicine.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using SPRAVATO

During and after each use of SPRAVATO, you will be checked by your doctor or other health care

professional who will decide how long to monitor you.

After being treated with this medicine, do not drive or use other machines that require you to be completely alert until the next day following a restful sleep.

Storage

Your doctor or healthcare professional will store your SPRAVATO for your use.

SPRAVATO should be kept in its original packaging in a cool dry place, where the temperature stays below 25°C

Disposal

Your doctor or healthcare professional will arrange to dispose of the device(s) and any medicine that is left over.

Do not take this medicine away from the clinic.

You must never be in direct possession of this medicine outside of the treatment site.

Product description

What it looks like

SPRAVATO is a nasal spray solution. It is a clear, colourless, aqueous solution provided in a pre-filled nasal spray device. Each nasal spray device is individually packaged in a sealed blister pack.

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

Ingredients

SPRAVATO contains 32.3 mg of esketamine hydrochloride (equivalent to 28 mg esketamine) as the active ingredient.

SPRAVATO also contains:

- Citric acid monohydrate
- Disodium edetate
- Sodium hydroxide

- Water for injections

SPRAVATO does not contain any preservatives, lactose, sucrose, gluten, tartrazine or any other azo dyes.

SPONSOR

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Registration numbers

SPRAVATO 28 mg per 2 actuations
(AUST R 311827)

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