



Your guide to treatment with **SPRAVATO**[®]

For people struggling with a psychiatric emergency
due to major depressive disorder (MDD-PE),
who have been prescribed SPRAVATO[®]

For further information on SPRAVATO[®], or if you experience any side effects,
speak to your doctor or nurse, or contact Janssen Medical Information on
[local markets to insert].

This includes any possible side effects not listed in the package leaflet. You can
also report side effects directly to the [insert local regulatory authority reporting
scheme for medicines, e.g. MHRA Yellow Card] at [insert URL, phone number
etc.] and to Janssen-Cilag Ltd. on [local markets to insert].

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Welcome to your SPRAVATO® guide

This booklet is for people who have been prescribed SPRAVATO® because they are experiencing a psychiatric emergency due to their major depressive disorder (MDD-PE).

You have been prescribed SPRAVATO® because you or your doctor have noticed a recent disruption to your behaviour, thoughts, or mood which may lead to harm.^{SUD,SPC}

This can mean many different things for different people suffering from depression. Whilst this can be unsettling, rest assured. There is help available.

This guide has been created to provide you with some information about SPRAVATO®. You will also find a few tools at the back of the guide to support you during the treatment process.

While the information here can provide some guidance, always consult your healthcare team (your doctor or a nurse) if you have any questions or concerns related to your treatment or symptoms.

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	To help you keep track of your treatment sessions and guide discussions with your healthcare team	

SPC SPRAVATO®, Summary of Product Characteristics. 2021.
SUD Sudarsanan S et al. Med J Armed Forces India 2004; 60(1): 59–62.



1.

SECTION 1

Your guide to SPRAVATO®

This section provides a quick overview of SPRAVATO®. If you have any further questions, please refer to Section 2 (beginning on Page 11) or speak with your healthcare team.



Why have I been prescribed SPRAVATO® therapy?

Your doctor has prescribed SPRAVATO® because you are experiencing a 'psychiatric emergency' due to your depression, and there is a need to get your depressive symptoms under control quickly.^{PIL}

SPRAVATO® **works differently** to other antidepressant treatments. It is also taken differently; as a **nasal spray in a healthcare setting**.^{SPC}

The **setting where you take SPRAVATO® may differ throughout your treatment**, depending on your **individual care plan** and what your healthcare team decide is best for you.

What can SPRAVATO® do for me?

SPRAVATO® can help to reduce symptoms of depression in a situation requiring immediate treatment.^{PIL}

In clinical trials where people struggling with a type of MDD-PE took SPRAVATO®:^{*,**,CAN}



Some people noticed a reduction in their depressive symptoms as soon as 4 hours after their first SPRAVATO® treatment session



After 1 day:^{CAN}
of people achieved remission of their depressive symptoms (having very few, or no, detectable symptoms of depression)



After 25 days:^{CAN}
of people achieved remission of their depressive symptoms

What side effects might I get with SPRAVATO®?

We know how worrying it is to experience a side effect and how much it may feel like taking a step backwards in your recovery.

A good way to manage any ups and downs is knowing what to expect. Here's a list of potential side effects which you may experience temporarily. This doesn't mean you definitely will but it's better to know what might come your way, so you can ask your doctor for advice.

If you experience any side effects, these may include:^{PIL}

- A feeling of disconnection from yourself, your thoughts, feelings or things around you (dissociation)
- Headache
- Spinning sensation (vertigo)
- Change in sense of taste
- Feeling sleepy
- Vomiting
- Decreased feeling or sensitivity, including around the mouth area
- Nausea
- Increased blood pressure
- Dizziness

When SPRAVATO® was taken in clinical trials, most people said any side effects they experienced were **mild or moderate** and **got better within an hour or two**, while they were still being looked after by a doctor or nurse.^{SPC,FU,ION}

Some people with certain cardiovascular or respiratory conditions will require additional care, so further precautions may be taken by the healthcare team.^{SPC}

For full details of all the possible side effects that can be experienced with SPRAVATO®, ask your healthcare team.



If you think you are experiencing or have experienced a side effect, it's important you let someone in your healthcare team know.

This is so that the medicine can be monitored to make sure it is safe for you and people in a similar situation. You can report any side effects in one of the following ways:

- Tell your healthcare team
- Ask someone to contact the [insert local regulatory authority reporting scheme for medicines, e.g. MHRA Yellow Card] at [insert URL, phone number etc.]
- Ask someone to contact the Janssen Medical Information team (Janssen are the company that make SPRAVATO®) on [insert contact details]

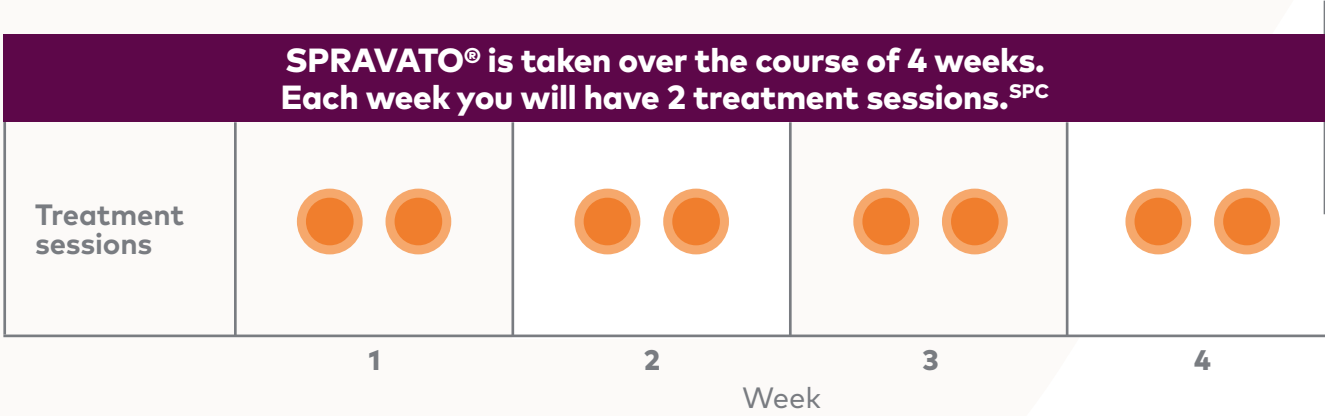
If you experience difficulty breathing or staying awake while using SPRAVATO®, let your healthcare team know immediately.^{PIL}

* SPRAVATO® was assessed in patients with MDD thinking about suicide, with intent to act on these thoughts.^{FU,ION}

** NOTE: SPRAVATO® has not been shown to prevent suicide or reduce suicidal thoughts or behaviours.^{SPC} People using SPRAVATO® may still need to go to hospital if their healthcare team decide this is for the best, even if they experience improvement following an initial dose of SPRAVATO®.^{SPC}

How often will I take SPRAVATO®?

SPRAVATO® is taken under the direct supervision of a healthcare professional,^{SPC} who will advise you on how and when to take the nasal spray.

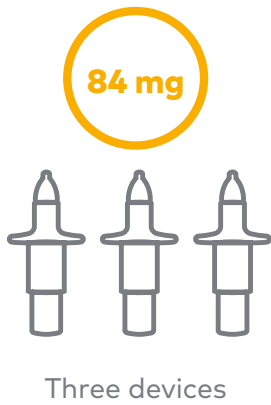


How much SPRAVATO® will I need to take?^{SPC,PIL}



In each session, it is recommended that you use three devices. If you experience any side effects, your doctor may reduce your dose.^{*,SPC}

One device contains 28 mg of SPRAVATO®
Each device delivers two sprays (one in each nostril)^{SPC}



84 mg

5 mins rest



between using each device

You will also take oral antidepressant therapy alongside SPRAVATO®

The oral antidepressant therapy should be continued (if the healthcare team decide this is for the best) after the 4 weeks of SPRAVATO® treatment has finished.^{SPC}

* Dose can be reduced to 56 mg (2 devices).^{SPC}

What will happen before I receive SPRAVATO®?

There are certain precautions that need to be taken immediately before and after receiving SPRAVATO® therapy.

If you are an outpatient coming in to the healthcare setting for your appointment, ensure you:^{SPC,PIL}

- Avoid any liquid intake for **30 minutes**
- Avoid using nasal corticosteroids or nasal decongestants for **1 hour**
- Avoid eating for **2 hours**

If you are returning home after your treatment session:^{SPC,PIL}

- **Do not drive, operate heavy machinery, or engage in any other activities that require complete mental alertness or coordination until the next day after a restful night's sleep**
- Use public transport or make plans for someone else to drive you home

If the person you care for is currently in hospital, the healthcare team can help take care of some of these for them.

What will happen when I take SPRAVATO®?



The healthcare professional will seat you in a calm environment and take your blood pressure.^{SPC} They'll then show you how to use the nasal spray.^{IFU}



After you have taken SPRAVATO®, your healthcare team will monitor any side effects you may experience.^{SPC}



The healthcare professional will also measure your blood pressure around 40 minutes after you have taken the full dose of SPRAVATO®, and as needed afterwards.^{SPC}

You should **let your healthcare team know if you are feeling unwell.**



They will monitor and care for you until they feel you have recovered from the treatment session and no longer require close monitoring.^{SPC}



How long do I need to take SPRAVATO® for?

SPRAVATO® is taken over the course of 4 weeks.^{SPC}

It is so important that you continue to take SPRAVATO® throughout the course of the 4 weeks as instructed by your doctor.

This is because if taken over the full course of treatment, SPRAVATO® can offer a chance to reduce your symptoms of depression.^{FU,ION}

After the 4 weeks of SPRAVATO® treatment has finished, it's likely that you will still need to continue to take the oral antidepressant therapy, depending on what your doctor thinks is best for you.^{SPC}

CAN Canuso CM et al. Poster 130. Presented at the 58th Annual Meeting of American College of Neuropsychopharmacology (ACNP), 8th–11th December 2019, Orlando, Florida, USA.
FU Fu DJ et al. J Clin Psychiatry 2020; 81(3). Published online. DOI: 10.4088/JCP.19m13191.
IFU SPRAVATO®, Instructions for Use. 2021.
ION Ionescu DF et al. Int J Neuropsychopharmacol 2021; 24(1): 22–31.
PIL SPRAVATO®, Patient Information Leaflet. 2021.
SPC SPRAVATO®, Summary of Product Characteristics. 2021.



SECTION 2

Q&A

If you have any questions about your SPRAVATO® therapy, we recommend that you first talk to your healthcare team. However, you can also find some answers to common questions in this section.

2.

Common questions about SPRAVATO®

1.

What is major depressive disorder? How is it normally treated?

Major depressive disorder (a type of depression, sometimes known as MDD for short) is what a lot of people might know as 'severe' or 'clinical' depression.

People who have depression have usually experienced sadness or low mood for at least 2 weeks, in addition to other potential symptoms, which can include:^{DSM}

- Losing interest or pleasure in things you once enjoyed
- Losing or gaining weight
- Having trouble sleeping, or sleeping a lot
- Feeling worthless or guilty
- Feeling less hungry nearly every day
- Feeling restless or slowed down to an extent other people have noticed
- Feeling fatigued (deeply tired)
- Trouble thinking or concentrating
- Thoughts of death, or ending your own life

It's estimated that over 40 million people in Europe have depression,^{WHO3} which means that more than 1 in every 20 people suffer with the condition.^{UNP}

In the event of a psychiatric emergency due to MDD, it's important to reduce any symptoms of depression as soon as possible.^{TYL} Unfortunately, many of the medications used to treat depression can take weeks or months to have an effect.^{TAY,GEL}

2.

What is a psychiatric emergency due to MDD (MDD-PE)?

A 'psychiatric emergency' is described as a recent disruption to someone's behaviour, thoughts, or mood which, if left untreated, may lead to harm.^{SUD,SPC} This can mean different things for different people, and is quite common for patients with depression.^{HAS2,HOL,FU} You should know that you are not alone, and there is help available – see section 3 of this guide (beginning on Page 19) for more information.

3.

How can patients in a psychiatric emergency due to MDD be treated?

There are many different treatments that doctors can use to help people with MDD who are experiencing a psychiatric emergency.^{WAS,S3G} Treatment options include medications which help to reduce symptoms of depression and anxiety, or to settle mood.^{WAS} For these treatments, individuals who present to an emergency department for urgent care may need to stay in hospital for a short while. On top of this, doctors may also suggest a talking therapy, such as cognitive behavioural therapy (CBT).^{WAS}

Note: These treatments are not specifically approved to treat psychiatric emergencies due to MDD, but they can be used by the healthcare team to help relieve some associated symptoms.

SPRAVATO® can also be prescribed (alongside oral antidepressant therapy) to quickly help reduce symptoms of depression at this time.^{FU,ION}

4.

Why do I have to take oral antidepressant therapy while I'm using SPRAVATO®?

You will be prescribed oral antidepressant therapy when you start taking SPRAVATO®.^{SPC}

It can take a while for some antidepressants to exert their full effects.^{TAY,GEL} Taking SPRAVATO® alongside these therapies can reduce depressive symptoms during this time.^{FU,ION}

After the 4 weeks of SPRAVATO® treatment have finished, it is likely that you will continue to take the oral antidepressant therapy.^{SPC}

You may also need to remain in hospital throughout your treatment and for a while afterwards, depending on what your healthcare team decide is right for your as part of your care plan.^{SPC}



Common questions about SPRAVATO®

5.

I think I'm experiencing a side effect with SPRAVATO® – what should I do?

Depending on the severity of your symptoms, there are a few things you can do in this situation.

If you are an inpatient, alert your healthcare team immediately and explain to them what you are experiencing.

It's especially important to let your healthcare team know straight away if you feel chest pain, shortness of breath, sudden severe headache, changes in vision, or seizures (fits) after using SPRAVATO®.

If you are an outpatient and have left the clinic, alert your healthcare team either using the contact information noted at the back of this booklet, or by dialling [local markets to insert contact details] in the event of an emergency.

6.

Why do I need to be monitored after I have taken SPRAVATO®?

More than 1,900 patients have taken SPRAVATO® in clinical trials to test how well it works as well as its safety profile.^{DAL2,CAN,CAN2,SPC}

Some people have reported certain side effects happening shortly after taking their dose of SPRAVATO® – you can read more about these on Page 7.

In the clinical trials where SPRAVATO® was tested, side effects usually got better on their own within a couple of hours and were rated as mild or moderate in severity.^{SPC}

SPRAVATO® may increase or decrease your blood pressure, or cause you to experience some things differently (for example sounds seeming louder or colours appearing brighter). This means you need to be supervised by your healthcare team for a short while after your treatment.^{SPC}

7.

Will I need to continue SPRAVATO® therapy if I leave the hospital?

SPRAVATO® therapy is taken over the course of 4 weeks.^{SPC} Your **healthcare team will decide when you are ready to leave the hospital based on your care plan.**

If you leave before the end of the 4 week period, you will need to travel into a healthcare clinic in order to complete the full course of treatment. This may be in a different location to where you first took SPRAVATO®. The healthcare team will advise you on where you need to go for your remaining treatment sessions. By completing the full course of treatment, you give yourself the best chance of reducing your depressive symptoms.^{FU,ION}

8.

Will my depressive symptoms come back again (relapse) when using SPRAVATO®, or after I stop therapy?

It is impossible to predict exactly what will happen when somebody stops taking a treatment. However, in clinical trials, 50% of people struggling with a type of clinical trials leading to the approval for MDD-PE? Achieved remission of their depressive symptoms after taking SPRAVATO® for 25 days.^{*CAN} This means they were experiencing very few, or no, detectable symptoms of depression.

If your healthcare team do advise you to stop using SPRAVATO® therapy, you should continue to:

- Listen to the advice of your psychiatrist, including taking any other medications they have prescribed
- Practice mental wellbeing exercises that you may have been taught
- Share your thoughts and feelings – if you feel like your mood might be worsening again let your healthcare team know as soon as possible
- Maintain your physical health by eating well, exercising, and avoiding recreational drugs or an excessive alcohol intake

* NOTE: SPRAVATO® has not been shown to prevent suicide or reduce suicidal thoughts or behaviours.^{SPC} People using SPRAVATO® may still need to go to hospital if their healthcare team decide this is for the best, even if they experience improvement following an initial dose of SPRAVATO®.^{SPC}

Common questions about SPRAVATO®

9.

Can I still take SPRAVATO® if I have other health problems or am taking other medications?

There are certain health conditions which may mean treatment with SPRAVATO® is not appropriate. These include conditions where a rise in blood pressure would lead to dangerous consequences, where the heart, blood vessels, lungs or breathing are affected, or for those with liver or kidney damage.^{SPC,PIL}

Other medications or substances (e.g. alcohol, recreational drugs, benzodiazepines, etc.) can affect how SPRAVATO® works, how it is removed from your body, or could make some side effects more severe.^{SPC}

Your doctor will have carefully assessed your general health and other medications you are taking before prescribing SPRAVATO®.^{SPC}

CAN Canuso CM et al. Poster 130. Presented at the 58th Annual Meeting of American College of Neuropsychopharmacology (ACNP), 8th–11th December 2019, Orlando, Florida, USA.

CAN2 Canuso CM et al. Am J Psychiatry 2018; 175(7): 620–630.

DAL2 Daly E et al. JAMA Psychiatry 2018; 75(2): 139–148.

DSM Diagnostics and Statistical Manual of Mental Disorders. Fifth Edition. 2013.

FU Fu DJ et al. J Clin Psychiatry 2020; 81(3). Published online. DOI: 10.4088/JCP.19m13191.

GEL Gelenberg AJ et al. Practice Guideline for the treatment of patients with major depressive disorder. Third edition. Part A-II-6, American Psychiatric Association 2010.

HAS2 Hasin DS et al. JAMA Psychiatry 2018; 75(4): 336–346.

HOL Holma KM et al. Am J Psychiatry 2010; 167(7): 801–808.

ION Ionescu DF et al. Int J Neuropsychopharmacol 2021; 24(1): 22–31.

PIL SPRAVATO®, Patient Information Leaflet. 2021.

S3G S3-Guideline/National Disease Management Guideline. Unipolar Depression (Short Version). 2009.

SPC SPRAVATO®, Summary of Product Characteristics. 2021.

SUD Sudarsanan S et al. Med J Armed Forces India 2004; 60(1): 59–62.

TAY Taylor D et al. The Maudsley Prescribing Guidelines in Psychiatry. 13th Edition. Chapter 3, Wiley Blackwell 2018.

TYL Tylee A, Walters P. BMJ 2007; 334(7600): 911–912.

UNP United Nations Population Division. World Population Prospects, the 2017 Revision. 2017. Available at: <https://population.un.org/wpp/Download/Standard/Population/>. Accessed March 2021.

WAS Wasserman D et al. Eur Psychiatry 2012; 27(2): 129–141.

WHO3 World Health Organisation. Depression and Other Common Mental Health Disorders: Global Health Estimates, 2017. Available at: <https://apps.who.int/iris/bitstream/handle/10665/254610/WHO-MSD-MER-2017.2-eng.pdf?sequence=1>. Accessed March 2021.





3.

SECTION 3 **Further support and tools**

In this section you will find useful tools and resources to help you through your SPRAVATO® therapy.


Useful contacts

Discuss with your healthcare team who your best point of contact will be throughout your treatment. This should include someone you can contact out of hours if and/or when you leave the healthcare setting. Note their names and details in these pages, so you have them ready for when you need them.


External points of support

There are several other points of contact you can use to find out more about your condition, or talk to someone in an impartial and confidential environment.


Support services **[to vary dependent on market] [For UK]:**




Mind
<https://www.mind.org.uk/>
0300 123 3393




Sane
<http://www.sane.org.uk/>
07984 967 708
[Temporary number to be used during COVID-19]




Mental Health UK
<https://www.mentalhealth-uk.org/>
020 7840 3008



Mental Health Foundation
<https://www.mentalhealth.org.uk/>
020 7803 1100



Rethink Mental Illness
<https://www.rethink.org/>
0300 5000 927



Samaritans
<https://www.samaritans.org/>
116 123

Contact form

If you have left the healthcare setting, note down the contact details of your healthcare team here so you have them to hand throughout your treatment.

Key contact	Details
GP	T: T (out of hours): M: Address:
Psychiatrist	T: T (out of hours): M: Address:
Nurse	T: T (out of hours): M: Address:
Non-emergency	[to be localised]
Emergency number	[to be localised]



Depressive symptom and side effect log

Use this log to note down and describe any symptoms or potential side effects you experience between treatment sessions, so you can inform your healthcare team.

Feel free to use this space to also note down any improvements, positive thoughts and feelings you may have, as these can be useful when talking to your doctor.

Remember to always let your healthcare team know if you experience any side effects during your treatment with SPRAVATO® therapy.

Note down as many details as possible, including:

- What did you feel?
- How long did it last?
- Did anything bring this on?
- Giving the symptom a rating - on a scale of 1 to 3, how strong was the effect? (1, mild; 2, moderate; 3, strong)

Date	Depressive symptom(s)	Date	Side effect(s)
1/10/20	Example: Negative thoughts are more intense this morning, feel as if I'll never be happy again. 3/3.	5/10/20	Example: Started eating dinner and it didn't taste quite right - started to feel nauseous and lost my appetite. 1/3.
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.../.../....		.../.../....	

Treatment diary

Here is a treatment diary that you can use with your healthcare team to keep track of your treatment sessions:

	Session 1	Session 2
Week 1	.../.../....	.../.../....
Week 2	.../.../....	.../.../....
Week 3	.../.../....	.../.../....
Week 4	.../.../....	.../.../....

Key definitions

MDD

Major depressive disorder. Symptoms of depressive mood and a loss of interest lasting at least 2 weeks, alongside three additional symptoms that are present at the time such as appetite loss, fatigue, and insomnia.^{DSM}

MDD-PE

Psychiatric emergency due to major depressive disorder. A term used to describe an episode of depression where someone experiences a recent disruption to their behaviour, thoughts or mood which, if left untreated, may lead to harm.^{SUD}

Relapse

When depressive symptoms start to come back after a period of feeling well again.^{FRA} Sometimes this can be caused by not taking medication correctly or often enough, but sometimes it can happen for no obvious reason.^{BUC,DUN2}

Remission

Feeling mostly or completely better.^{FRA} In this context means very few, or no, detectable symptoms of depression.^{FRA}

Dissociation

A side effect of treatment that some people may experience.^{SPC} In clinical trials, some people taking SPRAVATO® reported dissociation. Some patients have described this feeling as things seeming unreal, things moving in slow motion, the body feeling "changed" feeling "spaced out" or like they have lost track, feeling disconnected from their own body, and things feeling unclear or foggy.^{WIL4}

Sedation

A side effect that some people may experience.^{SPC} Described as feeling sleepy, calm or mellow. It may affect attention, judgment, thinking, reaction speed, and motor skills.^{SPC}

BUC Buckman JEJ et al. Clin Psychol Rev 2018; 64: 13–38.
DSM Diagnostics and Statistical Manual of Mental Disorders. Fifth Edition. 2013.
DUN2 Dunner DL et al. Prim Care Companion J Clin Psychiatry 2007; 9(3): 214–223.
FRA Frank E et al. Arch Gen Psychiatry 1991; 48(9): 851–855.
SPC SPRAVATO®, Summary of Product Characteristics. 2021.
SUD Sudarsanan S et al. Med J Armed Forces India 2004; 60(1): 59–62.
WIL4 Williamson D et al. Poster presented at The International Society for CNS Clinical Trials and Methodology (ISCTM) 15th Annual Scientific Meeting; 19–21 February, 2019, Washington DC, USA.

Notes pages

Use this space to write down any notes that you discuss with your healthcare team, or any questions that you might have.

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