



Caring for somebody who is receiving SPRAVATO[®] for treatment-resistant depression (TRD)

For further information on SPRAVATO[®], or if the person you are caring for experiences any side effects, speak to their 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 guide to caring for people who have been prescribed SPRAVATO®

This booklet provides you with further information about TRD and treatment with SPRAVATO®, to help you best understand the condition and treatment.

There is also a separate patient guide to SPRAVATO® to support them throughout their treatment. While the information here can provide some guidance, if you or someone you are caring for have further questions about TRD or SPRAVATO®, please speak to the healthcare team.



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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 a member of the healthcare team.



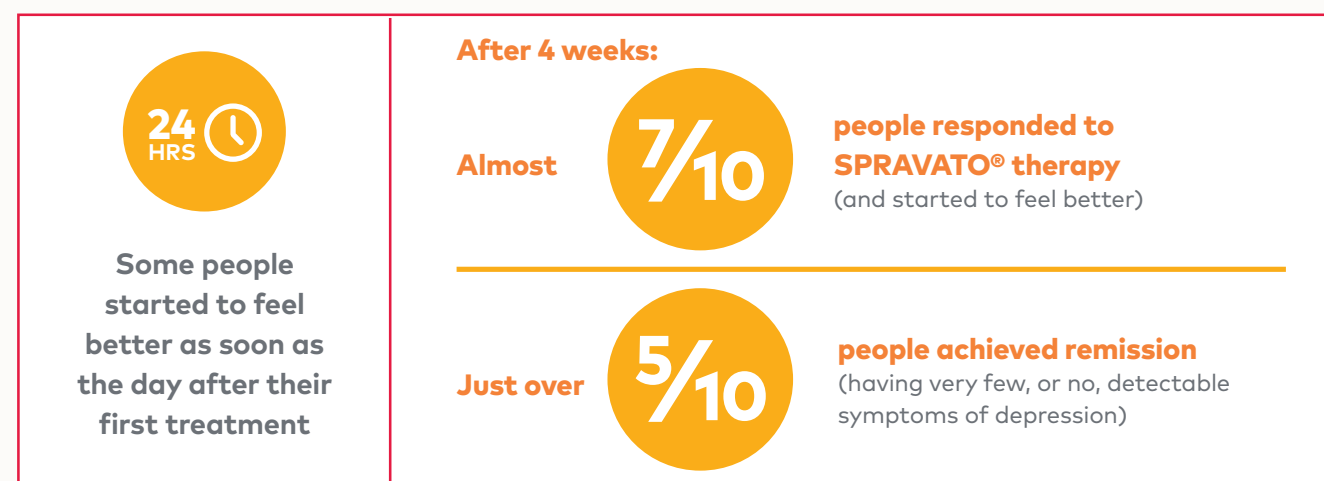
Why has the person I am caring for been prescribed SPRAVATO® therapy?

Their doctor has prescribed SPRAVATO® because they are going through an episode of depression that isn't getting better after trying at least two different treatments with antidepressants (ADs).^{PIL}

SPRAVATO® works differently to other AD treatments they may have tried. It is also taken differently; as a nasal spray in a healthcare setting.^{SPC}

How can SPRAVATO® help the person I am caring for?

In a short-term trial where people took SPRAVATO® for 4 weeks:^{POP}



In a long-term trial:^{WAJ}

People with TRD who took SPRAVATO® **started to feel better quickly**, and **for most people, the improvements lasted over the course of a year**.

As SPRAVATO® is taken at regular intervals, this provides the opportunity for the person you are caring for to meet regularly with their doctor or other healthcare professional. They can then continue to assess them at regular intervals to monitor how well SPRAVATO® is working for them.

What side effects might the person I am caring for experience with SPRAVATO®?

We know how worrying it can be for the person you're caring for to experience a side effect, and how it can feel like a step backwards in their recovery.

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

If the person you are caring for does experience any side effects, these may include:^{PIL}

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

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

Some people with certain cardiovascular or respiratory conditions will require additional care, so further precautions may be taken.

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



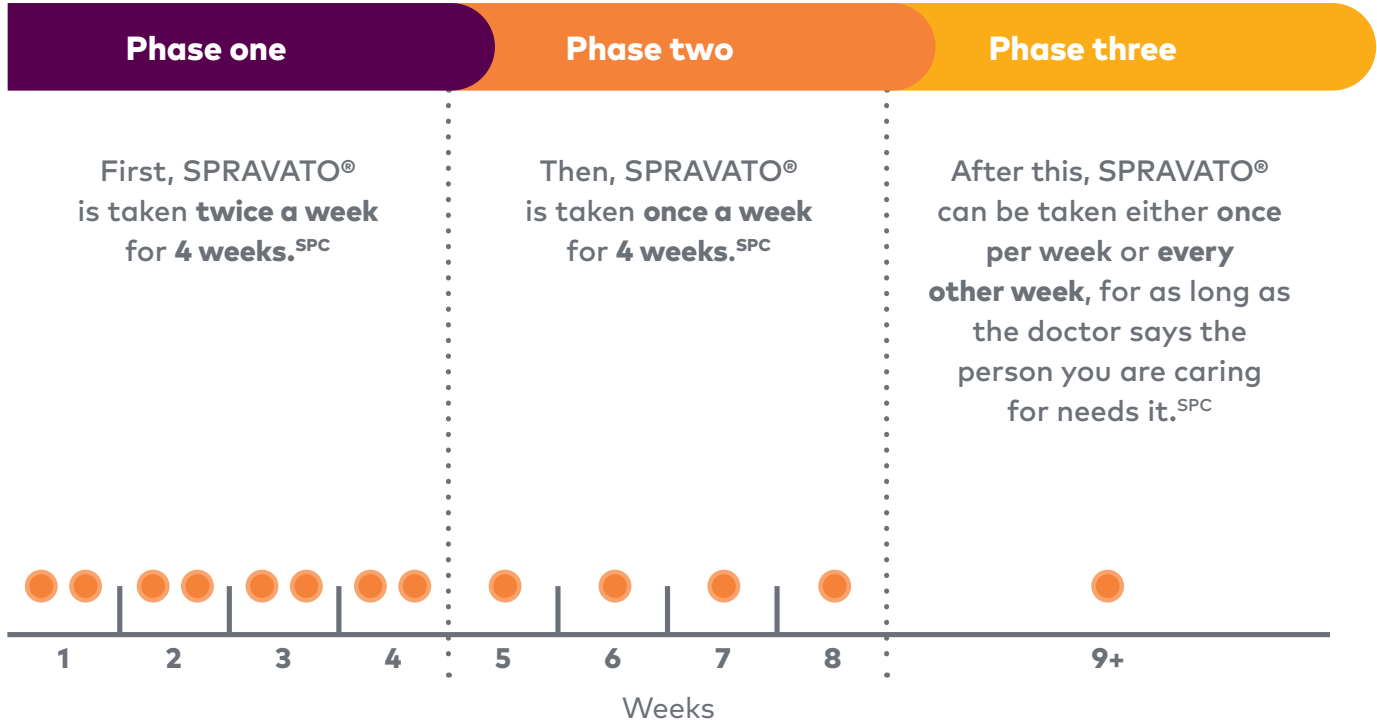
If you think the person you are caring for is experiencing or has experienced a side effect, either in the healthcare setting or later at home, it's important you let someone know. **This is so the medicine can be monitored to make sure it is safe for the person you are caring for and others. You can report any side effects in one of the following ways:**

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

If the person you are caring for experiences difficulty breathing or staying awake while using SPRAVATO®, contact the healthcare team immediately.^{PIL}

How often will the person I am caring for need to take SPRAVATO®?

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



How much SPRAVATO® will the person I am caring for need to take?^{SPC,PIL}



In each session, the person you are caring for may need to use up to three devices, depending on the dose their doctor thinks is best for them^{SPC}

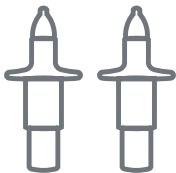
One device contains 28 mg of SPRAVATO®
Each device delivers two sprays (one in each nostril)^{SPC}

28 mg



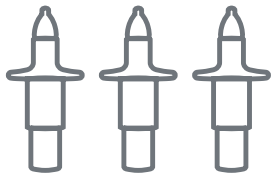
One device

56 mg



Two devices

84 mg



Three devices

5 mins rest



between using each device

Does the person I am caring for need to do anything to prepare for their appointments?

Immediately before their appointment they should:^{SPC,PIL}

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

After their appointment:^{SPC,PIL}

- They should 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
- They will need to travel home using public transport or make plans for someone else to drive them
- Elderly patients are at greater risk of falling and should be carefully monitored

What will happen during their appointments?



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



After they have taken SPRAVATO®, they will need to stay for a while so that the healthcare team can monitor them for any side effects they may experience.^{SPC} When SPRAVATO® was taken in clinical trials, **almost all** patients were ready to leave **within 90 minutes** of treatment and **almost half** of them were ready to leave **within an hour**.^{*,POP}



The healthcare professional will also measure their blood pressure around 40 minutes after they have taken SPRAVATO®, and as needed afterwards.^{SPC} If they seem unwell, **notify the healthcare team**.



The healthcare team will check on them until they feel they are ready to leave.^{SPC}



How long will the person I am caring for need to take SPRAVATO® for?

It is recommended that SPRAVATO® therapy should continue for **at least 6 months after they notice their mood improving**.^{SPC}

It is therefore important that the person you are caring for continues to attend their appointments and take SPRAVATO® as instructed by their doctor, even after they start to feel better.

Clinical trials have shown that if people with TRD respond to SPRAVATO® during their first 4 weeks of treatment, continuing treatment can help keep them well and reduce the risk of a relapse.^{DAL,WAJ}

* In the TRANSFORM-2 trial in TRD. Discharge time was assessed on each therapy day. Values of ≥44.3% and ≥93.2% represent when the lowest proportion of patients were ready for discharge at 60 and 90 mins respectively.^{POP}

DAL Daly E et al. JAMA Psychiatry 2019; 76: 893–903.
IFU SPRAVATO®, Instructions for Use. 2021.
PIL SPRAVATO®, Patient Information Leaflet. 2021.
POP Popova V et al. Am J Psychiatry 2019; 176(6): 428–438.
SPC SPRAVATO®, Summary of Product Characteristics. 2021.
WAJ Wajs E et al. J Clin Psychiatry 2020; 81(3). Published online. DOI: 10.4088/JCP.19m12891.



SECTION 2

Q&A

If you or the person you are caring for have any questions about SPRAVATO[®] therapy, we recommend that you first talk to the healthcare team.

However, you can also find some answers to common questions in this section, as well as in the patient guide.

2.

Common questions about SPRAVATO®

1.

What is depression? How is it normally treated?

Depression (also known as major depressive disorder, or MDD for short) is diagnosed when a person experiences a number of depressive symptoms for a period of 2 weeks or longer. These include; depressed mood, feeling fatigued, sleeping badly, or having trouble concentrating.^{DSM}

In Europe, it is estimated that over 40 million people suffer with depression,^{WHO3} which equates to more than 1 in every 20 people.^{UNP}

Depression is usually treated with a combination of talking therapies and medications.^{GEL,CLE}

For some people, finding a medication that works for them and helps relieve symptoms of depression is not always straightforward.^{ALH}

2.

The person I am caring for has been diagnosed with TRD – what does this mean? How is it treated?

Treatment-resistant depression (or TRD for short) is a term that can be used by doctors to describe a depression that is difficult to treat.

Usually this means that somebody going through an episode of depression isn't feeling sufficiently better even after trying at least two different treatments with antidepressants.^{EMA}

This can make TRD an especially difficult illness to live with.

However, it is important to remember that as many as one in three people with depression do not feel better even after trying several treatments – so it's a lot more common than you might expect.^{ALH}

TRD can be treated by using more than one medication at the same time, even if the person you are caring for has tried one of them previously.^{GEL,KEN} SPRAVATO® can be used to treat TRD alongside another antidepressant called a SSRI or a SNRI.^{SPC}

3.

What do I need to do before the person I am caring for starts taking SPRAVATO®?

Before starting SPRAVATO®, the doctor will ask them several questions to check that they can receive the therapy. You can also help, by letting their healthcare team know about:^{PIL,SPC}

- Any allergies or health conditions they have
- Other medicines they're currently taking or plan to take
- Changes to other medications they may be taking
- Use of non-prescription medicines or substances (i.e. off-the-shelf or over-the-counter medicines, alcohol, recreational drugs etc.)

This is because certain medicines and substances can affect how well SPRAVATO® works, how it is removed from the body, or can make certain side effects feel more severe.^{SPC}

If the person you are caring for is able to have a baby, the following must also be confirmed before using SPRAVATO®:

- They **must not be pregnant**, think they might be pregnant, or be planning to have a baby^{PIL}
- If **sexually active**, they must **use a highly effective method of contraception** during treatment, to ensure they don't become pregnant.^{PIL} Their doctor can advise on the best method of contraception
- If they are **breastfeeding**, they should consult their doctor for advice, so they can discuss the benefits of breastfeeding alongside the benefits of continuing treatment^{PIL}

4.

I've also heard SPRAVATO® being called 'esketamine' – does this mean it's like ketamine? Can it be addictive?

Researchers studied SPRAVATO® very carefully before the European Medicines Agency (EMA) approved it for use in TRD. It contains a medicine called esketamine.^{PIL}

You may have heard of ketamine, a drug similar to esketamine, being used as a veterinary medicine, or even a 'party' drug. It is actually an important medicine routinely used in medical treatments – usually to put people to sleep before they have a surgical operation.^{KET}

Researchers found that ketamine can help some people with depression feel better,^{BER} which led to the development of SPRAVATO®.

Key differences between SPRAVATO® and ketamine:

- Ketamine is given at higher doses than SPRAVATO®^{KET,SPC}
- Ketamine can be given through an intravenous drip (a needle in the arm), an injection, or taken orally. SPRAVATO® is taken as a nasal spray^{KET,SPC}

When people took SPRAVATO® in clinical trials, there were very few signs that they were becoming addicted (such as having cravings, becoming more tolerant or used to the effects, or having withdrawal symptoms).^{DAL,POR,FED,WAJ} This means it's unlikely the person you care for will become addicted to SPRAVATO® therapy.



Common questions about SPRAVATO®

5.

Why does the person I am caring for have to keep taking an oral antidepressant while being treated with SPRAVATO® therapy?

The person you are caring for can either continue on their current oral antidepressant or can be prescribed a new oral antidepressant when they start SPRAVATO®.^{SPC} This is there to help them make the most of their treatment and give them the best chance at relieving their depressive symptoms.

6.

How will the person I am caring for feel following SPRAVATO® treatment?

SPRAVATO® may cause some side effects (to read more on possible side effects of SPRAVATO®, please see Page 7). The person you are caring for will be carefully monitored by a healthcare professional following their treatment to ensure they are well. If you are accompanying them to a treatment session, you could ask to stay in the room with them whilst they receive their treatment for further support.

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

In clinical trials, when people experienced side effects these usually got better on their own within a couple of hours, and were rated as mild or moderate in severity.^{SPC}

7.

Is there anything the person I am caring for will need to do after the appointment?

They will not be able to drive, operate machinery, or engage in any other activities that require complete mental alertness or coordination, until the next day after a restful night's sleep.^{SPC} Therefore, they will need some help getting home or carrying out any other chores during this time.

Remind them to tell their doctor about any side effects they experience. You can help to record them in the treatment diary provided in the back of their patient guide, or note them down yourself in this booklet to provide a record for future reference.

8.

If I'm struggling, how can I reach out to others?

In a 2019 survey, carers reported they are nearly twice as anxious as the general population, and more than three quarters (81%) of carers reported feeling lonely or isolated.^{CAR1}

When caring for someone else it is so important to also take care of your own health. This can help you to avoid burnout and maintain your energy levels, so that you can give good support. If there is no one close to you or the person you are caring for available to support, it might be a good idea to consider contacting some external support services [each market to localise]. For more information, see Page 18.

Sharing experiences with other carers in a similar position to you is a good way to ease the stress you may be experiencing. Ask the healthcare team if they are aware of any carer support groups, or visit [insert resource location] to find support networks near you.

ALH Al-Harbi KS. Patient Prefer Adherence 2012; 6: 369–388.
BER Berman RM et al. Biol Psychiatry 2000; 47(4): 351–354.
CAR1 Carers UK. State of caring 2019. Available at: carersuk.org/stateofcaring. Accessed March 2021.
CLE Cleare A et al. J Psychopharmacol 2015; 29(5): 459–525.
DAL Daly E et al. JAMA Psychiatry 2019; 76: 893–903.
DSM Diagnostics and Statistical Manual of Mental Disorders. Fifth Edition. 2013.
EMA European Medicines Agency. Guideline on clinical investigation of medicinal products in the treatment of depression. 2013. EMA/CHMP/185423/2010. Rev. 2. 2013.
FED Fedgchin M et al. Int J Neuropsychopharmacol 2019; 22(10): 616–630.
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.
KET Ketalar 10 mg/ml injection, Summary of Product Characteristics. 2021.
PIL SPRAVATO®, Patient Information Leaflet. 2021.
POP Popova V et al. Am J Psychiatry 2019; 176(6): 428–438.
SPC SPRAVATO®, Summary of Product Characteristics. 2021.
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.
WAJ Wajs E et al. J Clin Psychiatry 2020; 81(3). Published online. DOI: 10.4088/JCP.19m12891.
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**

This section contains a number of additional resources and information on support services available to you.

Useful contacts

If you are caring for someone, there are several points of contact you can reach out to for support. This should include someone that you can contact out of hours. Note their names and details in these pages, so you have them ready for when you need them.

External points of support

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



Carers UK
<https://www.carersuk.org/>
020 7378 4999



Carers Trust
<https://carers.org/>
0300 772 9600



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



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



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



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

Contact form

Here is where you can note important contact details for the healthcare team so you always have them to hand.

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



Depressive symptom and side effect log

It might be helpful for both yourself and the person you are caring for to note down any symptoms or side effects they may experience.

This can then remind you both to mention them at their next appointment with the healthcare team.

For example, you might want to note down:

- Anything that stood out about how they appeared to feel, or said they felt
- Any noticeable mood changes
- Any event or trigger you think may have caused a change in mood

Date	Depressive symptom(s)	Date	Side effect(s)
1/10/20	Example: He had a much better night's sleep and said he felt in a better mood. Going to sleep earlier seemed to help him.	15/10/20	Example: I cooked dinner and he barely ate any of it, saying that he wasn't hungry. He said he felt nauseous and didn't eat much all day.
.../.../....		.../.../....	
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Treatment diary

Here is a treatment diary that you can use to keep track of their appointments with SPRAVATO® therapy.

Date	Frequency	Week 1	Week 2	Week 3	Week 4
.../.../....	Phase One Weeks 1–4 2 sessions per week	.../.../.... .../.../....	.../.../.... .../.../....	.../.../.... .../.../....	.../.../.... .../.../....
.../.../....	Phase Two Weeks 5–8 1 session per week	Week 5 .../.../....	Week 6 .../.../....	Week 7 .../.../....	Week 8 .../.../....
.../.../....	Phase Three Week 9+ 1 session per week or every 2 weeks	Week 9 .../.../....	Week/.../....	Week/.../....	Week/.../....

Key definitions

Dissociation

A side effect of treatment that some people may experience.^{SPC}
In clinical trials, some people taking SPRAVATO® described dissociation 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}

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}

Relapse

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

Remission

Feeling mostly or completely better. Meaning they ended up with very few, or no, detectable symptoms of depression.

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}

TRD

Treatment-resistant depression: A term used to describe an episode of depression where someone is not feeling better, even after trying at least two different treatments with antidepressants.

DSM Diagnostics and Statistical Manual of Mental Disorders. Fifth Edition. 2013.
SPC SPRAVATO® Summary of Product Characteristics. 2021.
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 the healthcare team, or any questions that you might have ahead of appointments.

