



Caring for somebody who is receiving SPRAVATO[®] for a psychiatric emergency due to major depressive disorder (MDD-PE)

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].

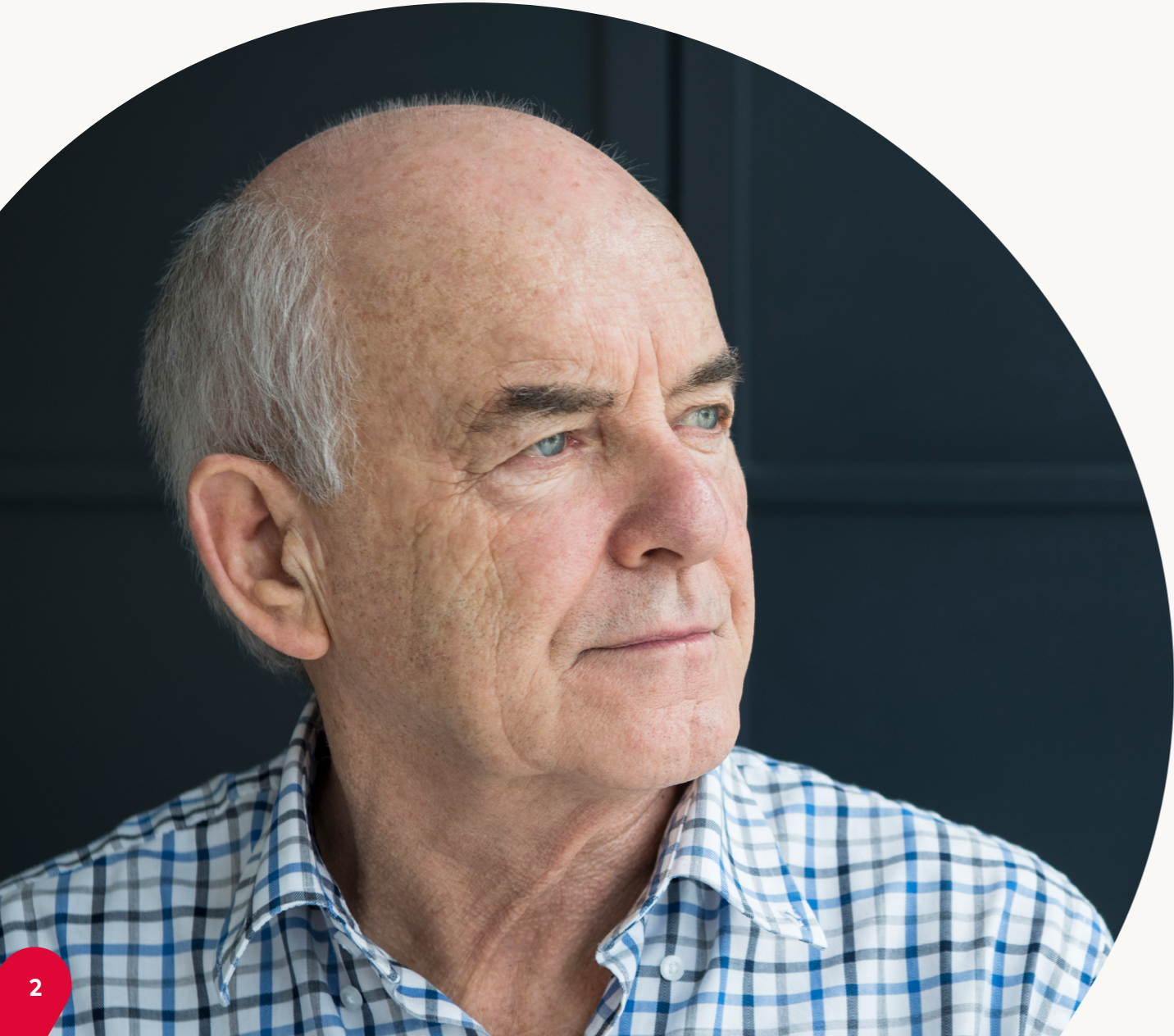
This includes any possible side effects not listed in the package leaflet. You can also report side effects directly to the [insert local regulatory authority reporting scheme for medicines, e.g. MHRA Yellow Card] at [insert URL, phone number etc.] and to Janssen-Cilag Ltd. on [local markets to insert].

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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 psychiatric emergencies due to major depressive disorder (MDD-PE), and treatment with SPRAVATO®, to help you best understand the condition and treatment.

There is also a separate SPRAVATO® patient guide to support the person you're caring for throughout their treatment. While the information here can provide some guidance, if either of you have questions about psychiatric emergencies due to MDD 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 experiencing a 'psychiatric emergency' due to their depression, and there is a need to get their depressive symptoms under control quickly.^{PIL,SPC}

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

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

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

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 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 for them to manage any ups and downs is knowing what to expect. Here's a list of potential side effects which they may experience temporarily.

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 any adverse events 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 the healthcare team.



If you think the person you are caring for is experiencing or has experienced a side effect, it's important you let someone in their healthcare team know.

This is so the medicine can be monitored to make sure it is safe for the person you are caring for and people in a similar situation. 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]

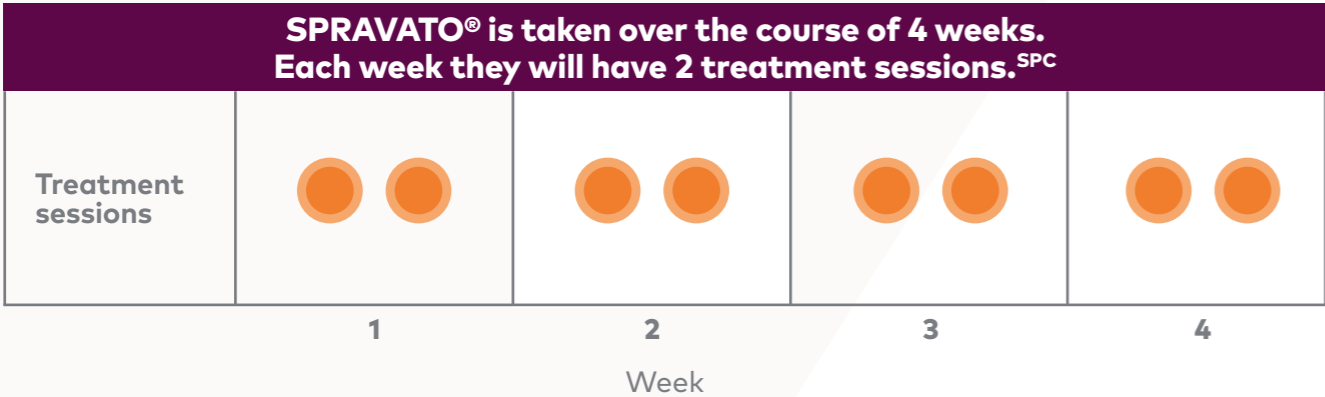
If you are with the person you are caring for and they experience any difficulty breathing or staying awake while using SPRAVATO®, let the healthcare team know immediately.^{PIL}

* 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 the person I am caring for 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.



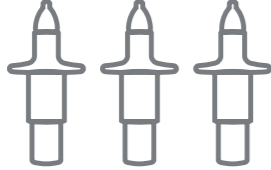
SPRAVATO® is taken alongside an oral antidepressant therapy, as part of the care plan.^{SPC}

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




In each session, it is recommended that the person you are caring for uses three devices. If they experience any side effects, their doctor may reduce their dose.^{*SPC}

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



84 mg

Three devices



5 mins rest

between using each device

The person you are caring for 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 the person I am caring for receives SPRAVATO®?

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

If they are an outpatient coming in to the healthcare setting for the appointment, they should:^{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 they are returning home after their treatment session:^{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 use public transport or make plans for someone else to drive them home
- If elderly, they will require careful monitoring as they may have a greater risk of falling

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 they take SPRAVATO®?




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®, the healthcare professional will monitor them for any side effects they may experience.^{SPC}



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



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



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

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

As a carer for someone experiencing a psychiatric emergency, it is so important that you support your friend, partner or family member throughout the course of their treatment.

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

After the 4 weeks of SPRAVATO® treatment has finished, it is likely that they will still need to continue to take the oral antidepressant therapy, depending on what their doctor thinks is best for them.^{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.

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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 major depressive disorder? How is it normally treated?

Major depressive disorder (a type of depression, sometimes known as 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}

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?

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}

Whatever symptoms your friend, partner or family member is experiencing, it's important to know that help is available – see section 3 of this guide (beginning on Page 17) 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.

What can I do to help the person I am caring for through their treatment with SPRAVATO®?

Before starting SPRAVATO®, the doctor will ask them several questions to check that they can receive the therapy. You can 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 treatment^{PIL}



Common questions about SPRAVATO®

5.

Why does the person I am caring for have to take oral antidepressant therapy alongside SPRAVATO®?

The person you are caring for will be prescribed oral antidepressant therapy when they 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 the person you are caring for will continue to take the oral antidepressant therapy.**

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

6.

Will the person I am caring for need to continue SPRAVATO® therapy if they leave the hospital?

SPRAVATO® therapy is taken over the course of 4 weeks.^{SPC} The **healthcare team will decide when the person you care for is ready to leave the hospital based on their care plan.** If they leave before the end of the 4 week period, they 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 they first took SPRAVATO®. The healthcare team will advise them on where they need to go for their remaining treatment sessions. By completing the full course of treatment, they give themselves them the best chance of reducing their depressive symptoms.^{FU,ION}

7.

If I'm finding it difficult to care for my friend or family member, how can I reach out to others?

In a 2019 survey, **carers reported feeling nearly twice as anxious as the general population,** and more than four in five carers (81%) 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 to offer extra support, it might be a good idea to **consider contacting some external 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 networks, or visit [insert resource location] to find help near you.

CAR1 Carers UK. State of caring 2019. Available at: carersuk.org/stateofcaring. Accessed March 2021.
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**

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:
Nurse	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 potential side effects they may experience during their treatment with SPRAVATO® therapy.

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 mentioned he'd been having intense negative thoughts today. He appears exhausted.	15/10/20	Example: He told me he hadn't eaten all day because he'd been feeling nauseous.
.../.../....		.../.../....	
.../.../....		.../.../....	
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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 may, if left untreated, 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® 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}
- 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 the healthcare team, or any questions that you or the person you are caring for might have.

