



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)
nasal spray

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.

SPRAVATO[®] (esketamine hydrochloride)

patient guide to treatment

This guide is intended for patients prescribed SPRAVATO.*

For further information on SPRAVATO or if you experience any side effects, speak to your healthcare professional.

*This document is one of two critical documents for patients for the administration of SPRAVATO that is considered part of the SPRAVATO Risk Minimisation Program.

Johnson & Johnson

Welcome to your SPRAVATO guide

SPRAVATO has been prescribed to you because you have tried other antidepressant medicines and have not benefited from them.¹

Using SPRAVATO can help improve your symptoms and reduce the chance of your symptoms coming back.¹

You will also find a few tools at the back of the booklet to support you during the treatment process.

The information in this booklet aims to provide you with guidance only. If you have any questions or concerns related to your treatment with SPRAVATO or experience any side effects, always consult the healthcare team at your SPRAVATO Treatment Centre.

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Why have I been prescribed SPRAVATO?

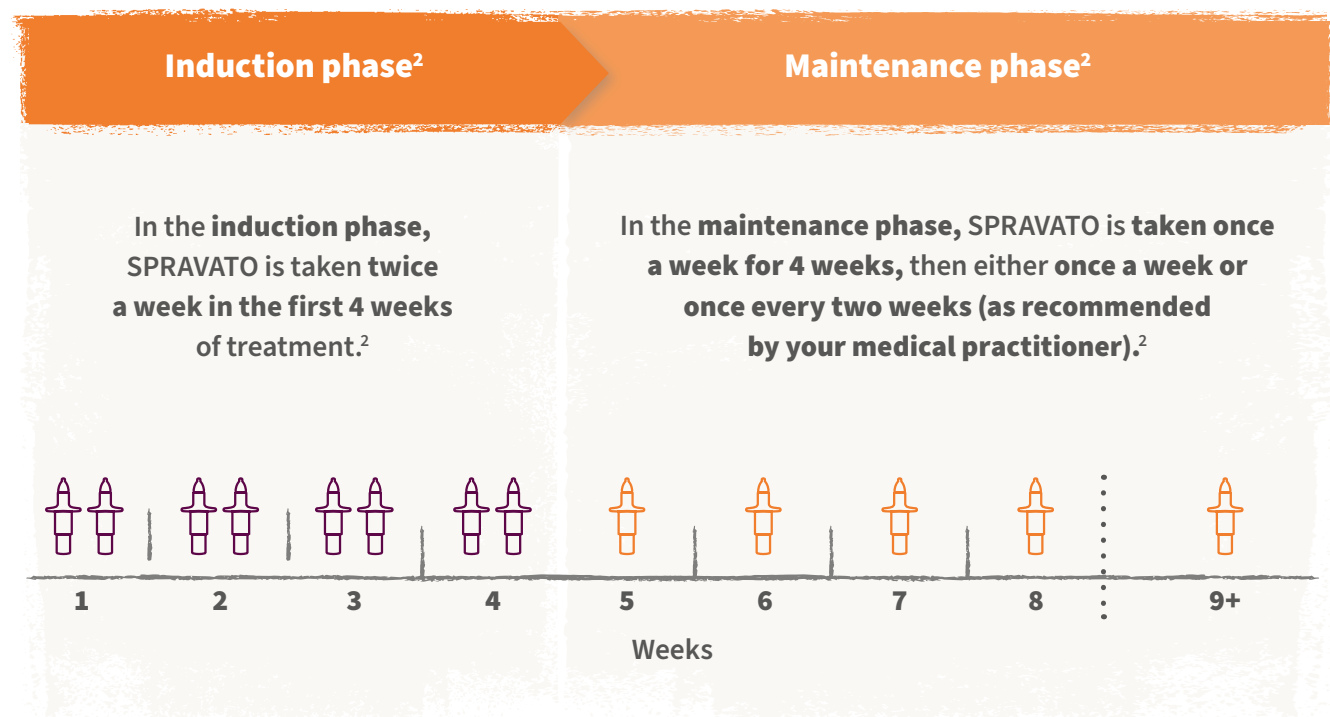
Your medical practitioner has prescribed SPRAVATO because you are going through an episode of depression that isn't getting better.¹

SPRAVATO works differently to other antidepressant treatments you may have tried in the past. It is also taken differently, as a nasal spray at your SPRAVATO treatment centre.¹



How often will I take SPRAVATO?

As SPRAVATO is taken at regular intervals, this gives you the opportunity to keep meeting with your healthcare team, who will work with you to make the most of every opportunity to help you get better, and continue to assess how well SPRAVATO is working for you.



How much SPRAVATO will I need to take?

You may need to use up to three devices at each appointment, depending on the dose your medical practitioner thinks is best for you.¹ Your treatment centre will have SPRAVATO ready for you at every appointment.²

One device contains 28 mg of SPRAVATO
Each device delivers two sprays (one in each nostril)²



One device



Two devices



Three devices

What side effects might I experience with SPRAVATO?

When starting a new medication, it is natural to feel concerned or worried about the potential side effects you might experience.

A good way to manage the ups and downs is knowing what to expect. Here's a list of potential side effects that you might temporarily experience. This doesn't mean you will experience all these side effects, you may not experience any of them. Understanding what side effects you may experience is important, so you can ask your healthcare professional about anything that concerns you.

If you experience side effects, these might include:¹

- feeling disconnected from yourself, your thoughts, feelings and things around you
- feeling anxious
- 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
- low blood pressure
- feeling extremely happy (euphoria)
- problems with thinking
- muscle tremors
- feeling very sleepy with low energy
- difficulty speaking
- difficulty breathing
- fast heartbeat
- nasal discomfort
- dry mouth
- excessive sweating
- frequent need to pass urine
- feeling abnormal
- feeling drunk
- increased saliva.

Note: This sticker was added to include the most up-to-date list of side effects.

Tell your healthcare professional if any of the above side effects worry you. In clinical trials, most of these were **mild or moderate and got better on the same day.**²

For further information, please speak to your healthcare professional or read the Consumer Medicine Information (CMI) leaflet available at www.janssen.com.au/spravato_cmi.



If you think you are experiencing or have experienced a side effect, either at your treatment centre or later at home, you should speak to your healthcare professional. In case of an emergency, dial 000 or go to the nearest hospital's Accident & Emergency Department.

Do I need to do anything before my appointments?

Before your appointment:¹

- Avoid eating **2 hours** before
- Avoid drinking any liquids **30 minutes** before
- Avoid using nasal sprays or nasal decongestants **1 hour** before.

After your appointment:¹

- **Do not drive or operate heavy machinery until the next day after a restful night's sleep**
- You will need to travel home using public transport or make plans for someone else to drive you home.

What will happen at my SPRAVATO appointments?



Your healthcare professional will review with you the step-by-step **How to self-administer card**, which shows you how to use the SPRAVATO nasal spray each time you have your treatment. Please ask your healthcare professional for a copy of the card and let them know **if you wish to review it before and/or after your treatment session.**



Your healthcare professional will seat you in a calm environment and take your blood pressure. They'll then show you how to use the SPRAVATO nasal spray.



After you have taken your SPRAVATO, you will need to stay for a while so that your healthcare professional can monitor any side effects you may experience. For awareness, in the SPRAVATO clinical trials, almost all patients were ready to leave within 90 minutes of treatment.²



You will be monitored to see if your blood pressure increases or if you experience any other side effects. After using SPRAVATO, your blood pressure may increase for a short time (about 1–2 hours). You should let your healthcare professional know if you are feeling unwell, sleepy or disconnected from yourself.



Your healthcare professional will let you know when they think you are ready to leave.



You will not be allowed to drive after your SPRAVATO treatment session, and so an alternative mode of transport home will need to be arranged.



How long do I need to take SPRAVATO?

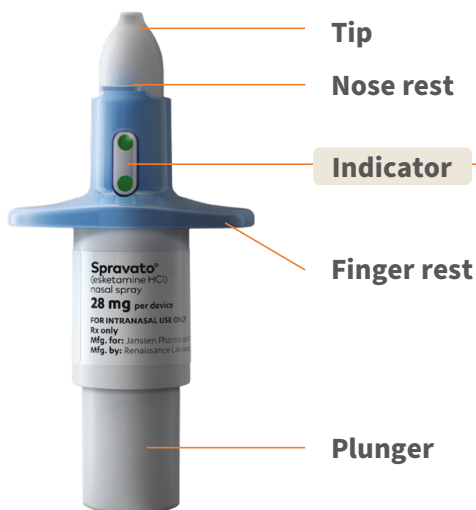
You should continue using SPRAVATO for as long as your medical practitioner tells you. It may be tempting to stop attending your treatment sessions if you start feeling better, but it is important to keep taking SPRAVATO and always follow the advice of your psychiatrist.

How do I self-administer SPRAVATO?

Important

This device is intended for administration by you, under the supervision of a healthcare professional and in a treatment centre.¹

Nasal Spray Device

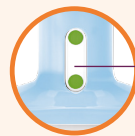


Each device delivers two sprays containing a total of 28 mg of medication.

Indicator

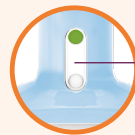
One device contains 2 sprays (1 spray for each nostril)

2 green dots



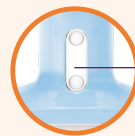
Device full

1 green dot



One spray delivered

No green dots – Two sprays (28 mg) delivered



Device empty

Step 1 Get ready¹

Before first device only:



Blow your nose before the first device only.



Confirm the number of devices you will need to use with the supervising healthcare professional.

28 mg = 1 device

56 mg = 2 devices

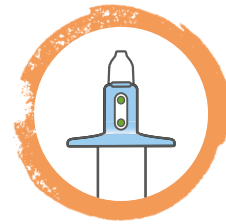
84 mg = 3 devices

Step 2 Healthcare professional will prepare device¹



Your supervising healthcare professional will:

- Check expiry date ('EXP'). If expired, they will get a new device.
- Open the packaging for you.



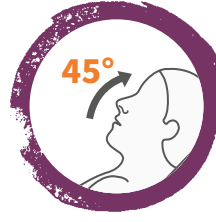
- Check that the indicator shows **2 green dots**. If not, they will get a new device.
- Hand you the device that is now ready for you to administer.

Step 3

Prepare for self-administration¹



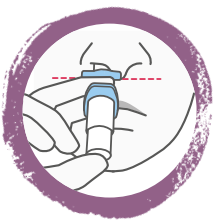
- Hold the device as shown with the thumb gently supporting the plunger.
- **Do not** press the plunger.



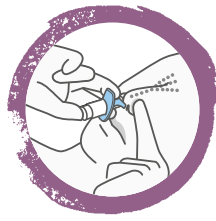
- Recline your head at about **45 degrees** during administration to keep the medication inside the nose.

Step 4

You are ready to self-administer¹



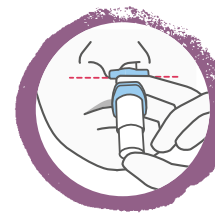
- Insert tip straight into the **first nostril**.
- The nose rest should touch the **skin between the nostrils**.



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



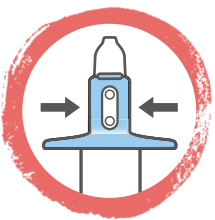
- **Sniff gently** after spraying to keep the medication inside the nose.



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

Step 5

Confirm delivery and rest¹



Your supervising healthcare professional will:

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



After delivery of the medication, you will:

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

⚠ Do not blow nose.

If you need to use another device:¹

IMPORTANT: Ensure that you **wait 5 minutes after each device** to allow medication to absorb.

28 mg 

56 mg 

84 mg 

- **Repeat Steps 2–5** for the next device.

Answers to frequently asked questions about depression and SPRAVATO

1.

What is major depressive disorder?

Major depressive disorder (sometimes known as MDD for short) is what a lot of people simply refer to as depression.³

People who have MDD usually have experienced sadness, or a low mood for a period of at least 2 weeks, in addition to other potential symptoms that can include:³

- Losing interest or pleasure in things you once found enjoyable
- Losing or gaining a lot of weight
- Having trouble sleeping or sleeping a lot
- Feeling worthless or guilty
- Having a decrease in your appetite nearly every day
- Feeling restless, or slowed down, to an extent other people have noticed
- Fatigued or tired
- Trouble thinking or concentrating
- Thoughts of death, or ending your own life
- Not going out anymore or withdrawing from close family, and friends.

It's important to remember that you are not alone. In fact, in Australia, more than 1.3 million people live with depression. That means approximately 1 in 20 people in Australia are living with depression.⁴

2.

How is MDD normally treated?

MDD is normally treated with a combination of psychological counselling and medications.⁵

However, for some people, finding a medication that works for them and helps relieve their depression is not always straightforward.⁶

3.

My healthcare professional mentioned that my depression is treatment resistant – what does this mean?

Healthcare professionals can sometimes describe depression that is difficult to treat as 'treatment-resistant depression' (or TRD for short).

Usually this means MDD isn't getting better, even after trying different medications.¹

However, it is important to remember that up to one in three people with MDD may not feel better even after trying several treatments, so it's a lot more common than you might expect.^{7,8}

4.

Why do I have to keep taking an oral antidepressant treatment while I'm having SPRAVATO?

Your medical practitioner will prescribe a new oral antidepressant when you start SPRAVATO therapy.¹ This oral antidepressant will be different to any you may have had before and is prescribed to help you make the most of your treatment, and give you the best chance at relieving your depressive symptoms.

5.

Can I take SPRAVATO if I'm pregnant, breast-feeding, or thinking of trying for a baby?

You cannot use SPRAVATO if you're pregnant, think you might be pregnant, or are planning to have a baby.¹

You cannot use SPRAVATO if you're breast-feeding. If you are breastfeeding, consult your healthcare professional before starting SPRAVATO treatment so they can advise on the best options for you and your child.¹

If you're sexually active, you must be using a highly effective method of contraception during your treatment. You must continue to use this for up to 6 weeks after stopping treatment, to ensure you don't become pregnant.¹ You can talk to your healthcare professional for advice on the best contraceptive option for you.

6.

Am I likely to gain weight with SPRAVATO?

In clinical trials where patients took SPRAVATO, they generally did not put on much weight.² This means it's unlikely your weight will change a lot, but you may still gain or lose a little.

7.

Will I become addicted to SPRAVATO?

When people took SPRAVATO in clinical trials, there were no signs that they were becoming addicted (such as having cravings, becoming more tolerant/used to the effects, or having withdrawal symptoms). This means it's unlikely you will become addicted to your SPRAVATO therapy.^{1,2}

Your healthcare professional will monitor you for any signs of SPRAVATO dependence. If they think you are at risk, they will discuss any concerns with you.

However, if you are worried you may be addicted to SPRAVATO, or you have had a history of addiction to illicit drugs, prescribed medications or alcohol, speak to your healthcare professional.^{1,2}

8.

Why do I need to take SPRAVATO in a treatment centre?

SPRAVATO needs to be taken in the presence of a healthcare professional, to ensure you administer it correctly and are receiving the correct amount of SPRAVATO.¹

You will also be monitored for a short while after you take your dose so that your healthcare professional can support you with any side effects you may experience immediately afterwards.¹

SPRAVATO is only available at your treatment centre and will be provided to you on the day of your treatment. You will not be able to pick up SPRAVATO from a pharmacy or be allowed to take it home with you.

9.

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

More than 1,700 people have used SPRAVATO in clinical trials.² Some people have reported certain side effects happening shortly after taking their dose of SPRAVATO. Usually these side effects got better on their own on the same day.^{1,2} You can read more about the potential side effects you may experience on page 6.

However, because SPRAVATO may increase or decrease your blood pressure, cause you to experience some things differently (for example sounds appearing louder or colours appearing brighter) and/or make you feel sleepy – you need to remain in your treatment centre until your healthcare professional decides that you are ready to leave.¹

10.

What should I do if I miss a SPRAVATO treatment session?

If you realise that you've missed a SPRAVATO treatment session, you should contact a member of your healthcare team straightaway.

They will tell you when to come in for your next appointment and manage what dose you will need to take.

11.

Am I likely to relapse when using SPRAVATO or after I stop therapy?

It is impossible to predict exactly what will happen when somebody stops taking a treatment. The best steps you can take after you have stopped receiving SPRAVATO are:

- Continue to visit your medical practitioner as recommended
- Ensure that you continue any mental well-being exercises that you may have been taught to support your mental health
- Continue to share your thoughts and feelings – if you feel like you might be experiencing a relapse or are starting to feel like the symptoms of depression are coming back, let your healthcare team know as soon as possible
- Work on maintaining your physical health: eat a well-balanced diet, keep up with a regular exercise routine, and avoid any recreational drugs or excessive alcohol intake.^{1,2}

I have other health problems – can I still take SPRAVATO?

People who have had certain health problems such as an ‘aneurysm’ (a weak spot in a blood vessel where it widens, or bulges out), or a history of bleeding in the brain should not take SPRAVATO. This is because SPRAVATO may cause a temporary rise in blood pressure, which for these people would be very dangerous.^{1,2}

SPRAVATO is broken down in the liver. This means for people with severe liver damage (sometimes called ‘hepatic impairment’), use of SPRAVATO is not recommended. However, for people with only mild or moderate liver damage, SPRAVATO may still be used.^{1,2}

Tell your healthcare professional if you have or have had any of the following medical conditions:¹

- 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.

Your healthcare professional will have carefully assessed your general health before prescribing SPRAVATO, and will only have prescribed it if they feel that it is appropriate for you.

I am taking other medications – can I still take SPRAVATO?

Tell your healthcare professional if you are taking any other medicines, including any that you get without a prescription from a pharmacy, supermarket or health food shop.¹

Some medicines and SPRAVATO may interfere with each other. These include:¹

- 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).

Your healthcare professional will have more information on the medicines you need to be careful with or that you should avoid completely while taking SPRAVATO.



**For further information, please read the
SPRAVATO Consumer Medicine Information
available at www.janssen.com.au/spravato_cmi**

Treatment tools

Depressive symptom and side effect log

Use this log to note down and describe any symptoms you experience between appointments so you can inform your healthcare team.

Feel free to use this space to also note down any successes, achievements, or positive thoughts and feelings you experience, as these may also be useful when talking to your healthcare professional.

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)
22/02/21	Example: Felt low this morning for no particular reason, didn't feel like getting up but improved as the day went on. 2/3.	25/02/21	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

Use this diary to keep track of your appointments with SPRAVATO therapy.

Date	Frequency	Week 1	Week 2	Week 3	Week 4
____/____/____	Weeks 1–4 2 sessions per week	____/____/____ ____/____/____	____/____/____ ____/____/____	____/____/____ ____/____/____	____/____/____ ____/____/____
____/____/____	Weeks 5–8 1 session per week	Week 5	Week 6	Week 7	Week 8
		____/____/____	____/____/____	____/____/____	____/____/____
____/____/____	Week 9+ 1 session per week or every 2 weeks (whilst prescribed) <i>[delete as appropriate]</i>	Week 9	Week	Week	Week
		____/____/____	____/____/____	____/____/____	____/____/____

Key definitions

Dissociation

A side effect of treatment that some people may experience.

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.^{2,9}

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.³

Relapse

When your 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.¹⁰

Remission

Feeling mostly or completely better.

Meaning they ended up with very few, or no, detectable symptoms of depression.¹¹

TRD

Treatment-resistant depression.

A term used to describe an episode of MDD where someone is not feeling better, even after trying two different antidepressant treatments.²

Notes

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



Information about depression

Beyond Blue

Provides information and support for people living with depression.

Phone: **1300 224 636**

Website: **beyondblue.org.au**

Black Dog Institute

A medical research institute that provides resources for people living with depression.

Website: **blackdoginstitute.org.au**

References: **1.** SPRAVATO (esketamine hydrochloride) Consumer Medicine Information. **2.** SPRAVATO (esketamine hydrochloride) Approved Product Information. **3.** Beyond Blue. Depression: Signs and symptoms. Available at: <https://www.beyondblue.org.au/the-facts/depression/signs-and-symptoms> (accessed March 2022). **4.** World Health Organization. Depression and other common mental disorders: Global health estimates. Available at: <https://apps.who.int/iris/bitstream/handle/10665/254610/WHO-MSD-MER-2017.2-eng.pdf> (accessed March 2022). **5.** Your Health in Mind. Depression. Available at: <https://www.yourhealthinmind.org/mental-illnesses-disorders/depression> (accessed March 2022). **6.** Beyond Blue. Treatments for depression. Available at: <https://www.beyondblue.org.au/the-facts/depression/treatments-for-depression> (accessed March 2022). **7.** Al-Harbi KS. *Patient Prefer Adherence* 2012;6:369–88. **8.** SANE Australia. Antidepressant medication. Available at: <https://www.sane.org/information-stories/facts-and-guides/antidepressant-medication> (accessed March 2022). **9.** Better Health Channel. Victoria State Government. Dissociation and dissociative disorders. Available at: <https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/dissociation-and-dissociative-disorders> (accessed March 2022). **10.** Healthline. Recognizing depression relapse: How to cope. Available at: <https://www.healthline.com/health/depression-relapse> (accessed March 2022). **11.** Culpepper L et al. *Am J Med* 2015;128:S1–S15.

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