

Readiness-to-leave checklist for healthcare professionals

Patient file number:.....
Date/Time of administration:.....
Time of readiness to leave:.....

At each treatment session, patients should be supervised during and after Spravato® (esketamine) nasal spray administration by a healthcare professional until they are stable, based on clinical judgement

The treating physician is responsible for deciding whether the patient is ready to leave based on this checklist and their clinical judgement.

Clinical assessments

- 1. Transient dissociative states and perception disorders (dissociation):** Have you confirmed that the patient does not have signs of dissociation or perceptual changes that might impair their functioning?
- 2. Disturbances in consciousness (sedation):** Have you confirmed that the patient is fully awake and responding to stimuli (i.e. not experiencing sedation)?
- 3. Blood pressure increased:** Are the patient's blood pressure values at acceptable levels?
- 4. Other adverse events:** Have any other adverse events resolved?

The patient

- 5.** Have you advised the patient that they should not drive or operate machinery until the next day following a restful sleep?
- 6.** Has the patient planned to travel home by public transport or arranged for someone else to drive them home?

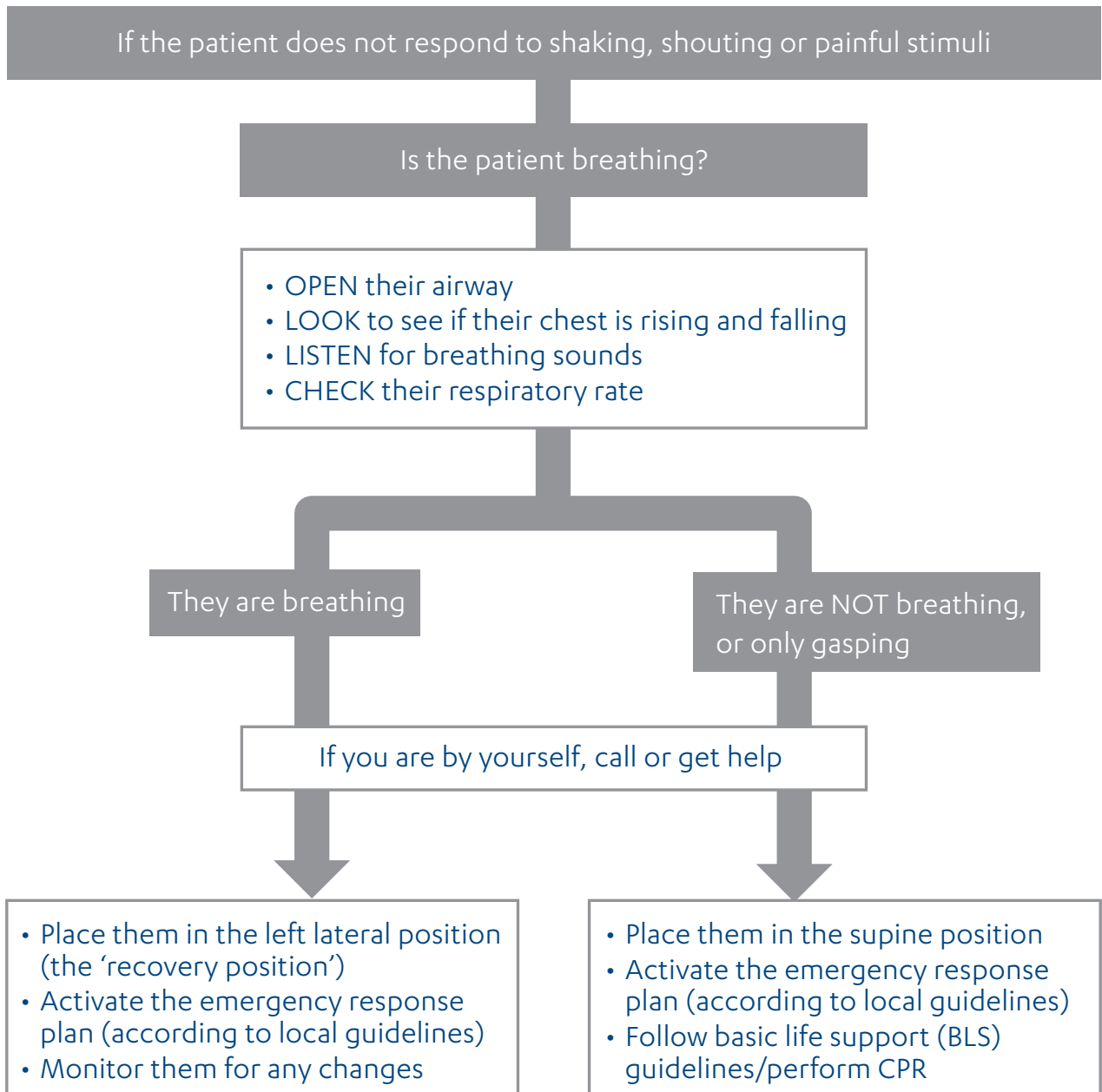
Readiness-to-leave

- 7.** Do you, the treating physician, believe the patient is ready to leave the healthcare facility based on your clinical judgement?



WARNING: Instruct patients not to engage in potentially hazardous activities, such as driving a motor vehicle or operating machinery, until the day after Spravato® administration following restful sleep.

What to do in an emergency



Signature:.....

What to do in an emergency

Contact information:

SFDA (National Pharmacovigilance and Drug Safety Department)

Email: npc.drug@sfda.gov.sa

Telephone: 19999

Fax: +966 11 2057662

Online: <http://ade.sfda.gov.sa>

For full prescribing information, please refer to the data sheet or contact

Johnson & Johnson Middle East FZ LLC, Saudi Branch at Mawheba

Building,3rd Floor, Al-Olaya Road, AlWaroud District P.OBox:55031

Riyadh:11533 Kingdom of Saudi Arabia Tel.: +966114339133 Fax:

=966112153190

To report Adverse Events/Product Complaint or any Medical Information

Inquiries, please contact us at Email: GCC-PV2@its.jnj.com

Hotline: 00966540015811

هيئة الغذاء والدواء (المركز الوطني للتبقيظ)

الخط المباشر: 19999
الإيميل: npc.drug@sfda.gov.sa

فاكس: 00966112057662

الموقع: as.vog.ads.eda.gov.sa

للحصول على معلومات عن طريقة استخدام الدواء , يرجى الرجوع الى النشرة الداخلية او

التواصل مع فرع جونسون أند جونسون ميدل ايست – السعودية في مركز الموهبة, الطابق

الثالث, شارع العليا, حي الورود, المملكة العربية السعودية, الرياض ص.ب 55031

الرياض: 33511 الهاتف: 00966114339133 فاكس: 00966112153190 .

للإبلاغ عن الأعراض الجانبية و شكاوى عن المنتجات او اي استفسارات طبية, يرجى

التواصل بنا عبر:

الإيميل: moc.jnj.sti@2VP-CCG

الخط المباشر: 00966540015811

For extra copies, please contact: +966114339133