



# South African Society of Psychiatrists

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## SASOP Statement on Use of IVI Ketamine and Intranasal Esketamine for TRD

Despite the proven efficacy of monoamine-based antidepressants, many treated individuals fail to achieve full syndromic and functional recovery, especially with repeated episodes. Ketamine and Esketamine represents novel treatment opportunities in the management of patients with treatment resistant depression (TRD) in Major Depression<sup>1</sup>.

Ketamine is registered in South Africa for anaesthetic induction, maintenance of general anaesthesia in combination with oxygen and nitrous oxide, and in children, management of minor surgery and diagnostic procedures.

Several studies and systematic reviews provide a good level of evidence for efficacy in the treatment of TRD, however concerns remain regarding long-term effects, side effects and safety issues. There is uncertainty regarding the position of novel treatments in treatment algorithms due to a lack of evidence in this regard.

Nevertheless, there is a rapid increase in the number of community-based clinics boasting the use of Ketamine in psychiatry. There are no guidelines or regulations available in the use of Ketamine in psychiatry in South Africa. This prompted the South African Association of Anesthesiologists (SASA) to publish a statement regarding safety concerns and measurement to put in place to ensure safe administration. SASA's concerns are regarding the administration and post administrative monitoring of patients. SASOP support the SASA statement.

SASOP has additional concerns regarding the selection of patients and long term follow up post treatment. Further concerns are around the psycho-memetic effect of Ketamine, especially in high-risk patients, and maintenance treatment. It is known that the antidepressant effect of administration of Ketamine wears off over time.

SASOP advises that the choice and initiation of treatment as well as follow up should be supervised by a psychiatrist. If the treatment is done by independent clinics the patient should be referred and followed up by a psychiatrist and referral notes and a discharge report should be kept for future reference. The use of IVI Ketamine and Esketamine in Psychiatric Disorders should be limited to TRD until more evidence is available for other disorders.

SASA guidelines have been drawn and approved for Ketamine implementation at point of care.

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## Key Messages

- Ketamine is emerging as a new treatment in psychiatry, but further active research is required to understand how to optimally use ketamine for treating mental illness. There is lack of evidence on its long-term effects, side effects and safety.
- At present there is sufficient evidence only for use in **treatment-resistant depression**, and not any other psychiatric conditions.
- Treatment-resistant depression needs to be managed on **level 2-7 care pathway i.e** by a **specialist psychiatrist**.
- At present the evidence is only sufficient for IV ketamine. There is not sufficient evidence to support the use of IM Ketamine, SC ketamine or Ketamine lozenges.
- IV Ketamine is registered in South Africa as an anaesthetic drug. According to a position statement by SASA, it must be administered by an **anaesthetist or a GP with a diploma in anaesthetics** in an environment where it possible to monitor the patient and potentially resuscitate.

## In Summary

Ketamine is a scheduled drug in South Africa. There is some evidence use for the off-label use in managing Treatment Resistant Depression.

Treatment Resistant Depression is managed on level 2-7 care pathways - that is the diagnosis, management and follow-up is done by a specialist psychiatrist.

To protect practitioners and patients, SASOP recommends the following:

1. The diagnoses, acute management and chronic management of Treatment Resistant Depression is managed on level 2-7 care pathway, led by a psychiatrist.
2. The administration of IV Ketamine is done by an anaesthetist or anaesthetically trained GP according to SASA protocols at the point of care.
3. There is no evidence for IM nor SC nor oral ketamine

**Esketamine (Spravato)** has been released in South Africa as an intranasally administered treatment. This is registered for treatment resistant depression (level 3 care) and has clear evidence-based guidelines for its use in acute and maintenance phase.

*SC = Subcutaneous*

*IM = Intramuscular*

*GP = General Practitioner*

*SASOP = South African Society of Psychiatrists*

*SASA = South African Society of Anesthetists*

<sup>i</sup> Jolien K.E.Veraart, Sanne Y.Smith-Apeldoorn, Harm-Pieter Spaans, Jeanine Kamphuis, Robert A.Schoevers; Is ketamine an appropriate alternative to ECT for patients with treatment resistant depression? A systematic review; *Journal of Affective Disorders*; Volume 281, 15 February 2021, Pages 82-89.

<https://reader.elsevier.com/reader/sd/pii/S0165032720330573?token=81CF1EA6C80D4D359A546116B701C3B9C6B3F9825B3F24AD4DC50989B9CEAC40B53C1A85D6E6A0164248703D3DA3C5D3&originRegion=eu-west-1&originCreation=20211013132613>

\* The Canadian Network for Mood and Anxiety Treatments (CANMAT) Task Force Recommendations for the Use of Racemic Ketamine in Adults with Major Depressive Disorder; *Recommandations Du Groupe De Travail Du Reseau Canadien, Pour Les Traitements De L'humeur Et De L'anxiété (Canmat), Concernant L'utilisation De La Ketamine Racémique Chez, Les Adultes Souffrant De Trouble Dépressif Majeur*

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\* Megan Brooks; Charles P. Vega; The APA Guidelines on Ketamine Use for Depression; <https://ketamineclinics.co.za/wp-content/uploads/2021/06/American-Psychiatric-Association-Guidelines-on-Ketamine-use-for-Depression.pdf>

\* Roger S. McIntyre, Joshua D. Rosenblat, Charles B. Nemeroff, Gerard Sanacora, James W. Murrough, Michael Berk, Elisa Brietzke, Seetal Dodd, Philip Gorwood, Roger Ho, Dan V. Iosifescu, Carlos Lopez Jaramillo, Siegfried Kasper, Kevin Kratiuk, Jung Goo Lee, Yena Lee, Leanna, Rodrigo B. Mansur, George I. Papakostas, Mehala Subramaniapillai, Michael Thase, Eduard Vieta, Allan H. Young, Carlos A. Zarate, Stephen Stahl, *Synthesizing the Evidence for Ketamine and Esketamine in Treatment-Resistant Depression: An International Expert Opinion on the Available Evidence and Implementation*; *ajp.psychiatryonline.org* 1; <https://adaa.org/sites/default/files/Banners/APA%20American%20Journal%20International%20Guidelines%20Ketamine%20Esketamine%20Final%202021.pdf>