pharmaceutically acceptable salts thereof. In certain examples, gaboxadol and ketamine are each provided at a synergistic dose, and may optionally be administered at the same time.

A method for reducing a risk of suicide and/or achieving a rapid-acting relief of depressive symptoms is disclosed comprising administering, a first treatment of gaboxadol, or pharmaceutically acceptable salt thereof, to a patient in need thereof in an amount sufficient to reduce the risk of suicide and/or to rapidly alleviate depressive symptoms, and optionally, administering a second treatment of gaboxadol, or pharmaceutically acceptable salt thereof, within less than 6 hours immediately following the administration of the first treatment, and if the patient experiences a recurrence of the risk of suicide and/or depressive symptoms, administering an additional treatment of gaboxadol, or pharmaceutically acceptable salt thereof, but not until at least 48 hours after the first treatment.

In one aspect, there is provided use of gaboxadol, or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for reducing a risk of suicide and/or achieving a rapid-acting relief of depressive symptoms, wherein a first treatment of gaboxadol, or pharmaceutically acceptable salt thereof, is to be administered to a patient, and optionally, a second treatment of gaboxadol, or pharmaceutically acceptable salt thereof, is to be administered within 12 hours immediately following the administration of the first treatment, and an additional treatment of gaboxadol, or pharmaceutically acceptable salt thereof, is to be administered but not until at least 3 days after the first treatment; wherein the rapid-acting relief of depressive symptoms is within 24 hours from the first treatment.

CLAIMS

What is claimed is:

1. Use of gaboxadol, or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for reducing a risk of suicide and/or achieving a rapid-acting relief of depressive symptoms, wherein

   a first treatment of gaboxadol, or pharmaceutically acceptable salt thereof, is to be administered to a patient, and

   optionally, a second treatment of gaboxadol, or pharmaceutically acceptable salt thereof, is to be administered within 12 hours immediately following the administration of the first treatment, and

   an additional treatment of gaboxadol, or pharmaceutically acceptable salt thereof, is to be administered but not until at least 3 days after the first treatment;

   wherein the rapid-acting relief of depressive symptoms is within 24 hours from the first treatment.

2. The use of claim 1, wherein the additional treatment of gaboxadol, or pharmaceutically acceptable salt thereof, is to be administered at least every 3, 4, 5, 6 or 7 days after the administration of the first treatment.

3. The use of claim 1 or 2, wherein the second treatment of gaboxadol, or pharmaceutically acceptable salt thereof, is to be administered within 12 hours immediately following the administration of the first treatment.

4. The use of claim 3, wherein the second treatment of gaboxadol, or pharmaceutically acceptable salt thereof, is to be administered after a neurological test of the patient demonstrates an insufficient response within 180 minutes immediately after administration of the first treatment.

5. The use of claim 4, wherein the insufficient response is an electroencephalogram (EEG) power density increase of less than 30% over baseline within 180 minutes after administration of the first treatment.

6. The use of claim 5, wherein the electroencephalogram (EEG) power density is calculated in a 0.25-8.0 Hz range.

7. The use of claim 5, wherein the electroencephalogram (EEG) power density is calculated in a 4.75-8.0 Hz range.

8. The use of claim 4, wherein the insufficient response is a whole head magnetoencephalography (MEG) planar gradiometer increase of less +3 in a combined delta, theta and alpha activity within 180 minutes after administration of the first treatment.

9. The use of any one of claims 1-8, wherein the use provides improvement in at least one symptom of risk of suicide selected from the group consisting of suicidal ideation, acute suicidality, recurrent thoughts of death, actions towards suicide and/or suicide attempts.

10. The use of any one of claims 1-9, wherein the patient is further diagnosed with a condition selected from the group consisting of suicidal ideation, acute suicidality, risk of self-harm and/or treatment-resistant depression.

11. The use of any one of claims 1-10, wherein the patient has not been previously treated with, or is not currently being treated with, or is not responding to an anti-depressive treatment.

12. The use of any one of claims 1-11, wherein the first treatment comprises 1 mg to 300 mg gaboxadol or a pharmaceutically acceptable salt thereof.

13. The use of any one of claims 1-12, wherein the first treatment comprises 33 mg to 300 mg gaboxadol or a pharmaceutically acceptable salt thereof.

14. The use of any one of claims 1-13, wherein the first treatment comprises 50 mg to 300 mg gaboxadol or a pharmaceutically acceptable salt thereof.

15. The use of any one of claims 1-14, wherein the first treatment is to be administered in an oral dosage form.

16. The use of any one of claims 1-15, wherein the oral dosage form is an orally disintegrating form.

17. The use of any one of claims 1-16, wherein the first treatment is to be administered intranasally.

18. The use of any one of claims 1-17, wherein the first treatment of gaboxadol, or pharmaceutically acceptable salt thereof, results in a blood level that is greater than 900 ng/ml.

19. The use of any one of claims 1-18, wherein a patient's plasma level of gaboxadol achieves an AUC_{0-2} of greater than 900 ng*hr/ml after administration of the first treatment.

20. The use of claim 19, wherein a plasma T_{max} of gaboxadol is achieved within 45 minutes after administration of the first treatment.

21. The use of claim 1, wherein the gaboxadol or salt thereof is to be administered before, after, or concurrently with any one of ketamine, SAGE-217, allopregnanolone, ganaxolone, alfadolone, alfaxolone, hydroxydione, minaxolone, pregnanolone, renanolone and other pregnane neurosteroids, AV-101 (L-4-Chlorokynurenine), rapastinel (GLYX-13), MGS0039, LY-341,495, MK-801 (dizocilpine), Ro 25-6981, rislenemdaz (CERC-301, MK-0657), apimostinel (NRX-1074), lanicemine (AZD6765), traxoprodil (CP-101606), (2R,6R)-hydroxynorketamine, decoglurant (INN) (RG1578, RO4995819), memantine, tiagabine, clozapine, [2-amino-4-(2,4,6-trimethylbenzylamino)-phenyl]-carbamic acid ethyl ester (AA29504) and pharmaceutically acceptable salts thereof.

22. The use of claim 21, wherein the gaboxadol or salt thereof is to be administered before, after, or concurrently with ketamine.

23. The use of claim 1, wherein the first treatment comprises a synergistic dose of gaboxadol, or pharmaceutically acceptable salt thereof, to be administered concurrently together with a synergistic dose of ketamine, wherein the synergistic dose of gaboxadol, or pharmaceutically acceptable salt thereof, is 20 mg or less and the synergistic dose of ketamine is 10 mg or less.

24. The use of claim 1, wherein the medicament is for reducing a risk of suicide and wherein the first treatment comprises gaboxadol at a dose of 5 mg to 50 mg in combination with ketamine.