Claims

1. A method of treating agitation associated with Alzheimer's disease in a subject, comprising administering to the subject therapeutically effective amounts of deuterated [d6]-dextromethorphan hydrobromide (d6-DM) and quinidine sulfate, wherein the subject is a patient that has been diagnosed as having Alzheimer's disease, wherein the method comprises determining the Cohen-Mansfield agitation inventory (CMAI) total score in the patient prior to said administration.

2. The method of claim 1, wherein the patient has been assessed as having a Cohen-Mansfield agitation inventory (CMAI) total score of greater than or equal to 32, such as 33 to 150, such as 45 to 120, such as 55 to 90.

3. A method of treating verbal agitation associated with Alzheimer's disease in a subject, comprising administering to the subject therapeutically effective amounts of deuterated [d6]-dextromethorphan, or a salt thereof, and quinidine, or a salt thereof, wherein the subject is a patient that has been diagnosed as having Alzheimer's disease, wherein the method comprises determining the CMAI verbally agitated behavior score in the patient prior to said administration.

4. The method of claim 3, wherein the method comprises determining the CMAI total score in the patient prior to said administration.

5. The method of claim 4, wherein the patient has been assessed as having a Cohen-Mansfield agitation inventory (CMAI) total score of greater than or equal to 32, such as 33 to 150, such as 45 to 120, such as 55 to 90.

6. The method of claim 4 or 5, wherein the patient has been assessed as having a CMAI verbally agitated behavior score of greater than or equal to 8, such as 8 to 28, such as 12 to 25, such as 12, 13, 14, 15, 16, 17, 18, 19 20, 21, 22, 23, 24, or 25.

~~7. The method of claim 6, wherein the patient has been assessed as having a CMAI verbally agitated behavior score of greater than or equal to 8.~~

~~8. The method of claim 6, wherein the patient has been assessed as having a CMAI verbally agitated behavior score of greater than 25.~~

~~9. The method of any one of the preceding claims, further comprising determining the CMAI total score in the patient following the administering step.~~

~~10. The method of any one of the preceding claims, further comprising determining the CMAI verbally agitated behavior score in the patient following the administering step.~~

~~11. The method of claim 10, wherein the difference between the CMAI verbally agitated behavior score in the patient prior to the administering step and the CMAI verbally agitated behavior score in the patient following the administering step is at least 1, such as 1 to 20, such as 2 to 20, such as 3 to 15, such as 4 to 15, such as 5 to 15, such as 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14 or 15.~~

~~12. The method of claim 10 or 11 wherein the CMAI verbally agitated behavior score in the patient following the administering step is at least 1% lower, such as 1% to 70% lower, such as 2% to 65% lower, such as 3% to 60% lower, such as 4% to 55% lower, such as 5% to 50% lower, such as 6% to 45% lower, such as 7% to 40% lower, such as 8% to 35% lower, such as 9% to 30% lower, such as 10% to 25% lower, such as 10% to 20% lower, such as 15% lower, than the CMAI verbally agitated behavior score in the patient prior to the administering step.~~

1. Use of therapeutically effective amounts of d6-DM and quinidine sulfate in the manufacture of a medicament for use in a method of treating agitation associated with Alzheimer's disease in a patient that has been diagnosed as having Alzheimer's disease, wherein the method comprises:

a) determining the Cohen-Mansfield agitation inventory (CMAI) total score in the patient;

and

b) administering the medicament to the patient.

2. The use of claim 1, wherein the effective amount of d6-DM is 28 mg.

3. The use of claim 1, wherein the effective amount of d6-DM is 42.63 mg.

4. The use of claim 1, wherein the medicament is formulated for twice daily administration.

5. The use of claim 1, wherein the medicament is formulated for once daily administration for a first week, and twice daily for each subsequent week.

6. The use of claim 1, wherein the medicament is formulated to reduce the CMAI total score in the patient by about 8 points to about 9 points, such as 8.1 points to 8.7 points after one week of administration.

7. The use of claim 1, wherein the medicament is formulated to reduce the CMAI total score in the patient by about 11 points to about 13 points, such as 11.0 points to 12.1 points after two weeks of administration.

8. The use of claim 1, wherein the medicament is formulated to reduce the CMAI total score in the patient by about 12 points to about 15 points, such as about 12 points to about 14 points, such as 12.6 points to 14.2 points after three weeks of administration.

9. The use of claim 1, wherein the medicament is formulated to reduce the CMAI total score in the patient by about 14 points to about 15 points, such as about 14.1 points to about 14.2 points after six weeks of administration.

10. The use of claim 1, wherein the medicament is formulated to reduce the CMAI total score in the patient by about 17 points to about 18 points, such as 17.0 points to 17.3 points after nine weeks of administration.

11. The use of claim 1, wherein the medicament is formulated to reduce the CMAI total score in the patient by about 16 points to about 19 points, such as 16.5 points to 18.9 points after twelve weeks of administration.

12. The use of claim 1, wherein the method comprises determining that the Cohen-Mansfield agitation inventory (CMAI) total score in the patient is from about 68 to about 72 prior to the administering step.

13. The use of claim 1, wherein the method comprises determining that the Cohen-Mansfield agitation inventory (CMAI) total score in the patient is from 68.8 to 71.3 prior to the administering step.

14. The use of claim 3, wherein the medicament is formulated to reduce the CMAI total score in the patient by about 8 points to about 9 points, such as about 8 points, such as 8.1 points after one week of administration.

15. The method of claim 3, wherein the medicament is formulated to reduce the CMAI total score in the patient by about 11 points to about 12 points, such as about 11 points, such as 11.0 points after two weeks of administration.

16. The use of claim 3, wherein the medicament is formulated to reduce the CMAI total score in the patient by about 12 points to about 13 points, such as about 13 points, such as 12.6 points after three weeks of administration.

17. The use of claim 3, wherein the medicament is formulated to reduce the CMAI total score in the patient by about 14 points to about 15 points, such as about 14 points, such as 14.1 points after six weeks of administration.

18. The use of claim 3, wherein the medicament is formulated to reduce the CMAI total score in the patient by about 17 points to about 18 points, such as about 17 points, such as 17.3 points after nine weeks of administration.

19. The use of claim 3, wherein the medicament is formulated to reduce the CMAI total score in the patient by about 18 points to about 19 points, such as about 19 points, such as 18.9 points after twelve weeks of administration.

20. The use of claim 3, wherein the method comprises determining that the Cohen-Mansfield agitation inventory (CMAI) total score in the patient is from about 71 to about 72, such as about 71, such as 71.3, prior to the administering step.

21. The use of claim 1, wherein the patient has been assessed as having a CMAI aggressive behavior score of greater than or equal to 15.

22. The use of claim 21, wherein the patient has been assessed as having a CMAI aggressive behavior score of 15 to 40.

23. The use of claim 1, wherein the patient has been assessed to have a score of 2 to 7 for at least one CMAI aggressive behavior item selected from the group consisting of;

1) hitting (including self);
2) kicking;
3) grabbing onto people;
4) pushing;
5) throwing things;
6) biting;
7) scratching;
8) spitting;
9) hurting self or others;
10) tearing things or destroying property;
11) screaming; and
12) cursing or verbal aggression.

24. The use of claim 23, wherein the patient has been assessed to have a score of 2 to 5 for the at least one CMAI aggressive behavior item.

25. The use of claim 5, wherein the medicament is formulated for administration of effective amounts of d6-DM and quinidine sulfate once daily for a first week, and twice daily for each subsequent week for 11 weeks.