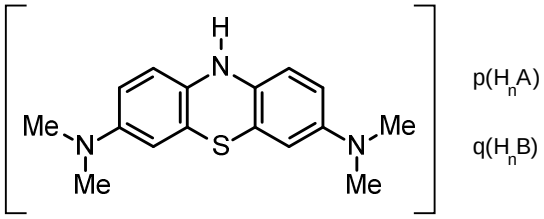
Claims

1. Use of a therapeutic methylthioninium (MT)-containing compound in the preparation of a medicament for the therapeutic treatment of Alzheimer's disease or Mild Cognitive Impairment in a subject,

wherein said MT-containing compound is to be administered to said subject,

wherein the MT-containing compound is an LMTX compound of the following formula:



wherein each of H_nA and H_nB (where present) are protic acids which may be the same or different,

and wherein p = 1 or 2; q = 0 or 1; n = 1 or 2; (p + q) × n = 2,

or a hydrate or solvate thereof,

wherein said subject is selected from the following groups:

(i) a subject who has not historically received treatment with a neurotransmission modifying compound which is a modifier of the activity of acetylcholine or glutamate neurotransmitters; or

(ii) a subject who has historically received treatment with a neurotransmission modifying compound which is a modifier of the activity of acetylcholine or glutamate neurotransmitters, but ceased that treatment at least 3, 4, 5, 6, 7, or 8 weeks prior to treatment with the LMTX compound;

wherein said therapeutic treatment with LMTX is maintained for treatment timeframe without co-administration with a neurotransmission modifying compound which is a modifier of the activity of acetylcholine or glutamate neurotransmitters

followed by;

treatment with LMTX with co-administration of a neurotransmission modifying compound which is a modifier of the activity of acetylcholine or glutamate neurotransmitters.

wherein the treatment timeframe prior to co-administration of the therapeutic compound with the neurotransmission modifying compound is at least 2 months.

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2. The use as claimed in claim 1 wherein said therapeutic treatment with LMTX comprises a total daily dose of between 2 and 100 mg of MT to the subject per day, optionally split into 2 or more doses.

3. The use as claimed in claim 2 wherein the total daily dose of MT is from 10 - 60 mg or from 20 – 40 mg.

4. The use as claimed in claim 3 wherein the total daily dose is from any of 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20 mg to any of 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60 mg.

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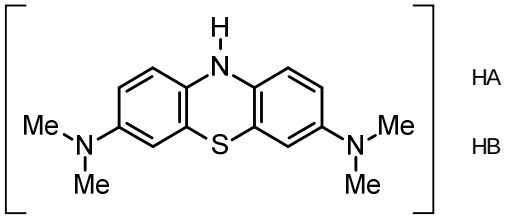
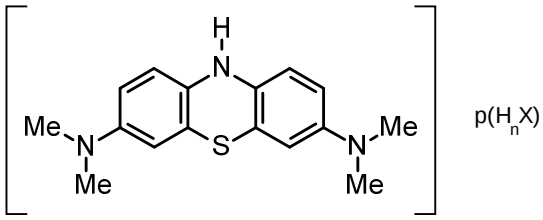
5. The use as claimed in any one of claims 1 to 4 wherein

(a) the LTMX compound has the following formula, where HA and HB are different mono-protic acids:



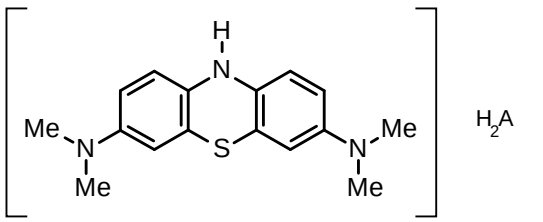
or

(b) the LTMX compound has the following formula:

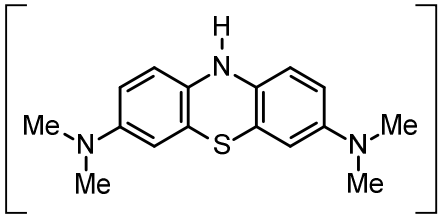


wherein each of H_nX is a protic acid, or.

(c) the LTMX compound has the following formula and H_2A is a di-protic acid:



6. The use as claimed in claim 5 wherein the LTMX compound has the following formula and is a bis-monoprotic acid:



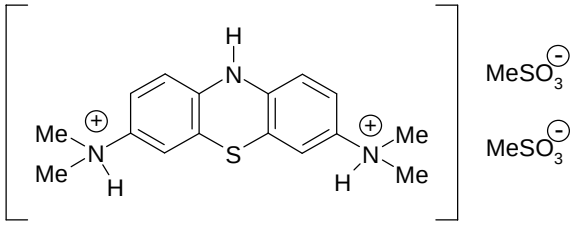
2(HA)

7. The use as claimed in any one of claims 1 to 6 wherein the or each protic acid is an inorganic acid, which is optionally a hydrohalide acid such as HCl; HBr or which is optionally HNO_3; or H_2SO_4.

8. The use as claimed in any one of claims 1 to 6 wherein the or each protic acid is an organic acid.

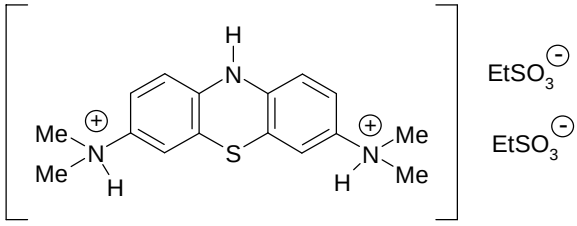
9. The use as claimed in claim 8 wherein the or each protic acid is selected from H_2CO_3; CH_3COOH; methanesulfonic acid, 1,2-ethanedisulfonic acid, ethanesulfonic acid, naphthalenedisulfonic acid, p-toluenesulfonic acid.

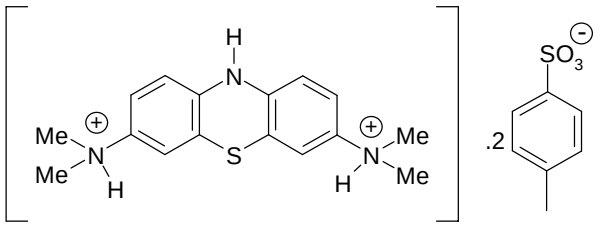
10. The use as claimed in claim 9 wherein the LTMX compound is LMTM:

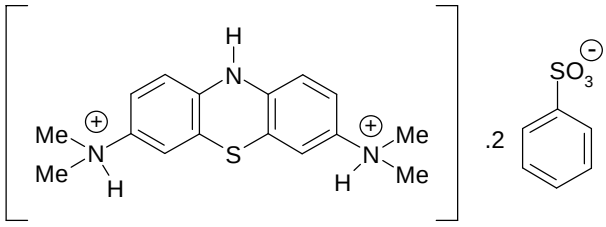


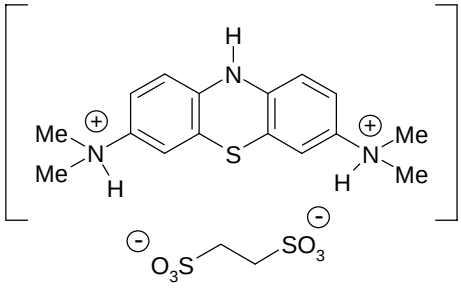
11. The use as claimed in claim 10 wherein said therapeutic treatment with LMTX comprises a total daily dose of LMTM of 34 to 67, 34 to 100, 34 to 134, or 34 to 167 mg/day optionally wherein the dose of LMTM is about 34, 67, or 100 mg/once per day.

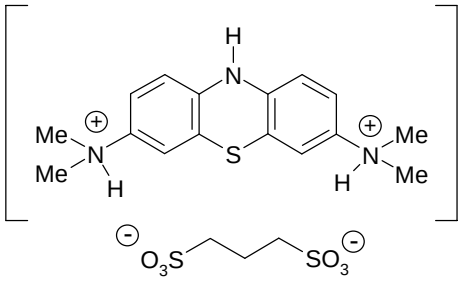
12. The use as claimed in any one of claims 1 to 4 wherein the LTMX compound is selected from the list consisting of:

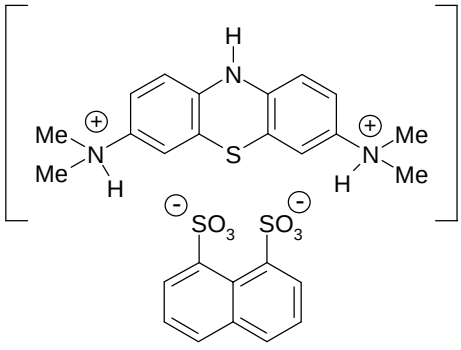












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13. The use as claimed in any one of claims 1 to 12 wherein the LTMX compound is provided as a pharmaceutical composition comprising the LMTX compound and a pharmaceutically acceptable carrier or diluent in the form of a dosage unit, which is optionally a tablet or capsule.

14. The use as claimed in claim 13 wherein the amount of MT in the unit is 4, 5, 6, 7, 8, 9, 10, 20, or 30 to 40, 50 or 60 mg.

15. The use as claimed in claim 13 wherein the dosage unit comprises 34 to 67 mg, 34 to 100, 34 to 134, or 34 to 167 LMTM.

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16. The use as claimed in any one of the preceding claims wherein the treatment timeframe prior to any co-administration of the therapeutic compound with the neurotransmission modifying compound is at least 6 months.

17. The use as claimed in any one of the preceding claims wherein the treatment prior to any co-administration of the therapeutic compound with the neurotransmission modifying compound is a monotherapy.

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18. The use as claimed in any one of the preceding claims wherein the subjects who have historically received treatment with a neurotransmission modifying compound which is a modifier of the activity of acetylcholine or glutamate neurotransmitters, have ceased that treatment at least 6 weeks prior to said treatment or assessment.

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19. The use as claimed in any one of the preceding claims, wherein the neurotransmission modifying compound is an acetylcholinesterase inhibitor.

20. The use as claimed in any one of claims 1 to 19, wherein the neurotransmission modifying compound is selected from donepezil; rivastigmine; and galantamine.

21. The use as claimed in any one of claims 1 to 18, wherein the neurotransmission modifying compound is an N-methyl-D-aspartate receptor (NMDA) receptor antagonist.

22. The use as claimed in any one of claims 1 to 18 or claim 21, wherein the neurotransmission modifying compound is memantine.