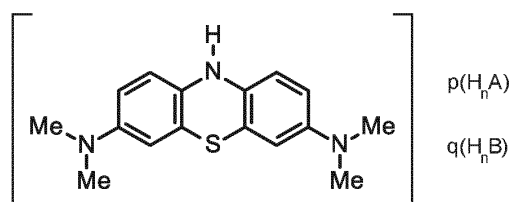


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Claims

1. A method of therapeutic treatment of COVID-19 in a subject,
 which method comprises administering to said subject a methylthioninium (MT)-
 containing compound,
 wherein said administration provides a total daily oral dose of between 10 and 30
 mg of MT to the subject per day, optionally split into 2 or more doses,
 or wherein said administration provides a total daily intravenous (IV) dose of
 between 10 and 25 mg of MT to the subject per day,
 wherein the MT-containing compound is an LMTX compound of the following
 formula:

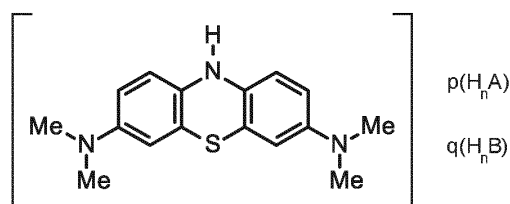


wherein each of H_nA and H_nB (where present) are protic acids which may be the same or
 different,
 and wherein p = 1 or 2; q = 0 or 1; n = 1 or 2; (p + q) × n = 2,
 or a hydrate or solvate thereof.

2. A method as claimed in claim 1 wherein the subject is a human who has been
 diagnosed with COVID-19, or wherein said method comprises making said diagnosis.

3. A method of prophylactic treatment of COVID-19 in a subject,
 which method comprises administering to said subject a methylthioninium (MT)-
 containing compound,
 wherein said administration provides a total daily oral dose of between 10 and 30
 mg of MT to the subject per day, optionally split into 2 or more doses,
 or wherein said administration provides a total daily intravenous (IV) dose of
 between 10 and 25 mg of MT to the subject per day,
 wherein the MT-containing compound is an LMTX compound of the following
 formula:

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

5 and wherein $p = 1$ or 2 ; $q = 0$ or 1 ; $n = 1$ or 2 ; $(p + q) \times n = 2$,
or a hydrate or solvate thereof.

4. A method as claimed in claim 3 wherein the subject is a human who has been
assessed as having suspected or probable COVID-19.

10 5. A method as claimed in claim 4 wherein the subject is selected from: a subject
who has been in close contact with one or more COVID-19 cases; a subject who is at
least 65 years old; a subject living in a nursing home, care home, or long-term care
facility; a subject with a relevant underlying medical condition.

15 ***

20 6. A method as claimed in any one of claims 1 to 5 wherein the total daily dose is
between 10 and 25 mg MT (IV) or 12 and 27 mg MT (oral).

7. A method as claimed in claim 6 wherein the total daily dose is between 14 and
20mg MT.

25 8. A method as claimed in claim 7 wherein the total daily dose is between 15 and 18
mg MT.

9 A method as claimed in any one of claims 1 to 5 wherein the total daily dose is
about 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, or 30
30 mg MT.

10 A method as claimed in any one of claims 1 to 5 wherein the total daily dose is
about 16 mg MT.

35 11 A method as claimed in any one of claims 1 to 10 wherein the total daily dose of
the MT-containing compound is administered as a split oral dose twice a day or three
times a day, or is a continuous infusion IV dose, or is an intermittent IV dose which is
optionally 2, 4, or 6 times a day.

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12 A method as claimed in any one of claims 1 to 11 wherein the treatment is combined with a second compound which is chloroquine or hydroxychloroquine.

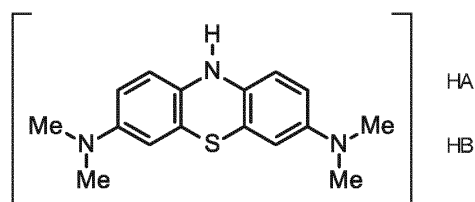
13 A method as claimed in any one of claims 1 to 11 wherein the treatment is combined with a second compound or agent selected from: lopinavir-ritonavir; arbidol; azithromycin, remdesivir, favipiravir, actemra; dexamethasone; convalescent plasma.

14 A method as claimed in claim 12 or claim 13 wherein the MT-containing compound and the second compound or agent are administered sequentially within 12 hours of each other.

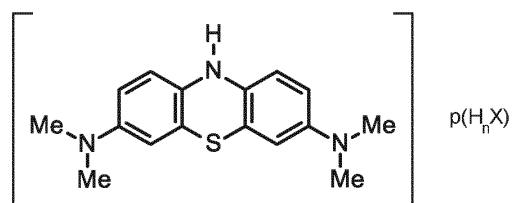
15 A method as claimed in any one of claims 12 to 14 wherein the subject is pre-treated with the second compound or agent prior to commencement of the treatment with the MT-containing compound.

16 A method as claimed in claim 12 or claim 13 wherein the MT-containing compound and the second compound are administered simultaneously, optionally within a single dosage unit.

17. A method as claimed in any one of claims 1 to 16 wherein the MT-containing compound has the following formula, where HA and HB are different mono-protic acids:



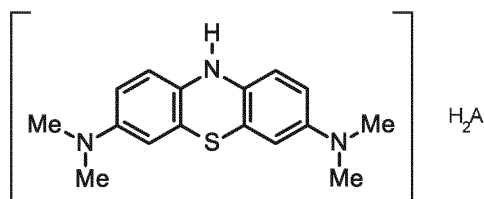
18. A method as claimed in any one of claims 1 to 16 wherein the MT-containing compound has the following formula:



wherein each of H_nX is a protic acid.

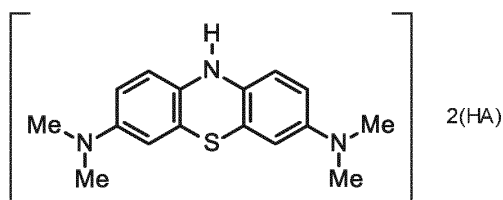
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19. A method as claimed in any one of claims 1 to 16 wherein the MT-containing compound has the following formula and H₂A is a di-protic acid:



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20. A method as claimed in claim 18 wherein the MT-containing compound has the following formula and is a bis-monoprotic acid:



10

21. A method as claimed in any one of claims 1 to 20 wherein the or each protic acid is an inorganic acid.

22. A method as claimed in claim 21 wherein each protic acid is a hydrohalide acid.

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23. A method as claimed in claim 21 wherein the or each protic acid is selected from HCl; HBr; HNO₃; H₂SO₄.

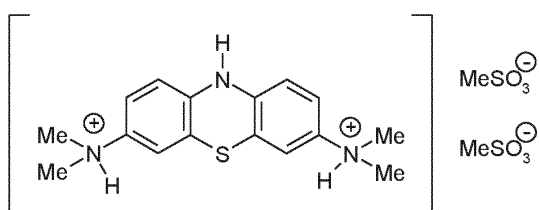
24. A method as claimed in any one of claims 1 to 20 wherein the or each protic acid is an organic acid.

20

25. A method as claimed in claim 24 wherein the or each protic acid is selected from H₂CO₃; CH₃COOH; methanesulfonic acid, 1,2-ethanedisulfonic acid, ethansulfonic acid, naphthalenedisulfonic acid, p-toluenesulfonic acid.

25

26. A method as claimed in any one of claims 1 to 20, or claim 25 wherein the MT-containing compound is LMTM:

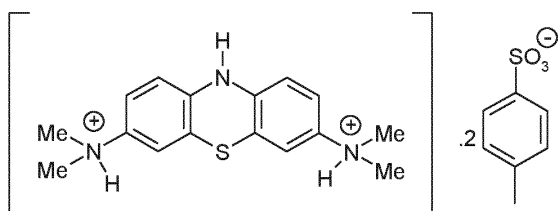
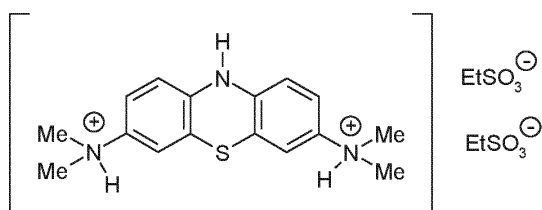


27. A method as claimed in claim 26 wherein the total daily dose of LMTM is around 17 mg/day.

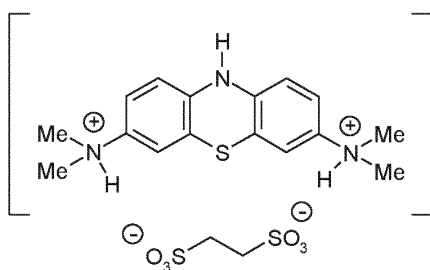
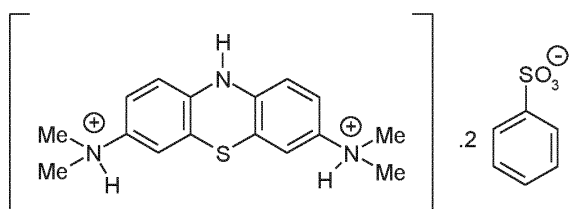
5 28. A method as claimed in claim 27 wherein the dose of LMTM is about 27 mg/once per day.

29. A method as claimed in any one of claims 1 to 20 wherein the MT-containing compound is selected from the list consisting of:

10

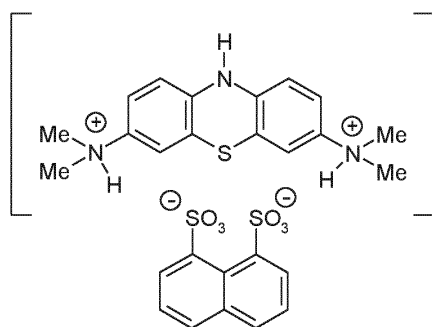
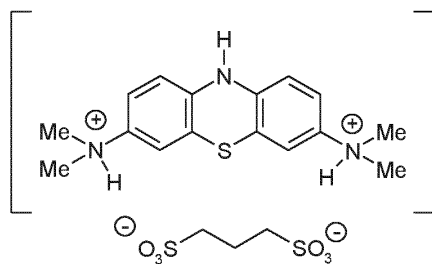


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30. An MT-containing compound as defined in any one of claims 1 to 29, for use in a method of treatment as defined in any one of claims 1 to 29.

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31. Use of an MT-containing compound as defined in any one of claims 1 to 29, in the manufacture of a medicament for use in a method of treatment as defined in any one of claims 1 to 29.