CLAIMS

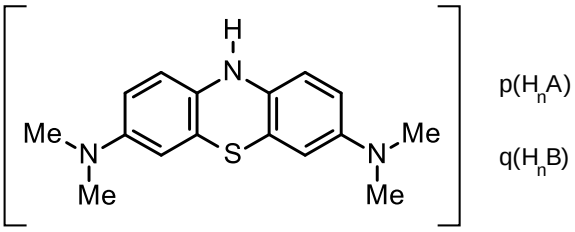
1. Use of an MT-containing compound in the manufacture of a medicament for use in a ~~A~~ method of therapeutic or prophylactic treatment of COVID-19 in a subject,

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~~has 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~~The use 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.

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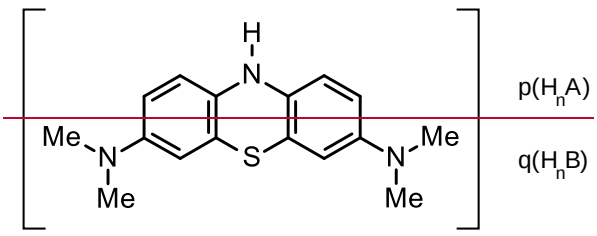
~~3. A method of prophylactic treatment of COVID-19 in a subject,~~

~~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:~~



~~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.~~

~~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.~~

~~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.~~

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36. ~~A method~~The use ~~-~~ as claimed in any one of claims 1 to 2~~5~~ wherein the total daily dose is between 10 and 25 mg MT (IV) or 12 and 27 mg MT (oral).

47. ~~A method~~The use ~~-~~ as claimed in claim 3~~6~~ wherein the total daily dose is between 14 and 20mg MT.

58. ~~A method~~The use ~~-~~ as claimed in claim 4~~7~~ wherein the total daily dose is between 15 and 18 mg MT.

69 ~~A method~~The use ~~-~~ as claimed in any one of claims 1 to 2~~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 mg MT.

7~~10~~ ~~A method~~The use ~~-~~ as claimed in any one of claims 1 to 2~~5~~ wherein the total daily dose is about 16 mg MT.

8~~11~~ ~~A method~~The use ~~-~~ as claimed in any one of claims 1 to 7~~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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9~~12~~ ~~A method~~The use ~~-~~ as claimed in any one of claims 1 to 8~~11~~ wherein the treatment is combined with a second compound or agent which is selected from the list consisting of: 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.

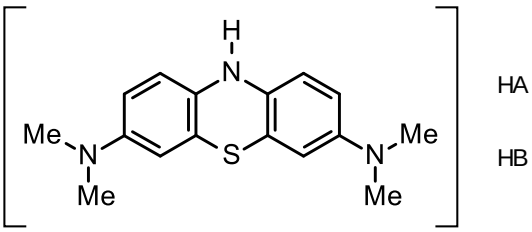
10~~14~~ ~~A method~~The use~~-~~ as claimed in claim 9~~12 or claim 13~~ wherein the MT-containing compound and the second compound or agent are administered sequentially within 12 hours of each other.

11~~15~~ ~~A method~~The use~~-~~ as claimed in any one of claims 9~~12~~ to 10~~14~~ wherein the subject is pre-treated with the second compound or agent prior to commencement of the treatment with the MT-containing compound.

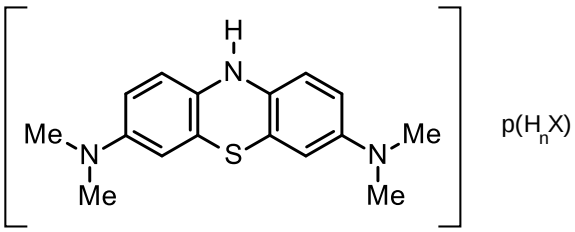
12~~16~~ ~~A method~~The use~~-~~ as claimed in claim 9~~12 or claim 13~~ wherein the MT-containing compound and the second compound are administered simultaneously, optionally within a single dosage unit.

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13~~17~~. ~~A method~~The use~~-~~ as claimed in any one of claims 1 to 12~~16~~ wherein the MT-containing compound has the following formula, where HA and HB are different mono-protic acids:

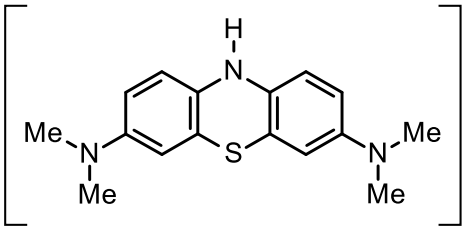


14~~18~~. ~~A method~~The use~~-~~ as claimed in any one of claims 1 to 12~~16~~ wherein the MT-containing compound has the following formula:



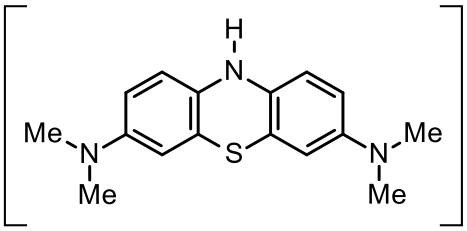
wherein each of H_nX is a protic acid.

15~~19~~. ~~A method~~The use~~-~~ as claimed in any one of claims 1 to 12~~16~~ wherein the MT-containing compound has the following formula and H_2A is a di-protic acid:



H_2A

1620. ~~A method~~The use~~-~~ as claimed in claim 1418 wherein the MT-containing compound has the following formula and is a bis-monoprotic acid:



2(HA)

1721. ~~A method~~The use~~-~~ as claimed in any one of claims 1 to 1620 wherein the or each protic acid is an inorganic acid.

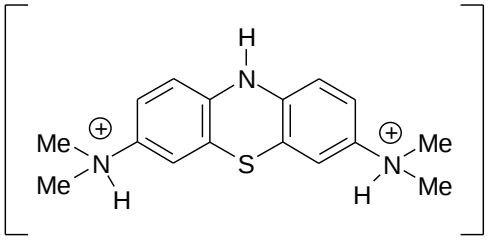
1822. ~~A method~~The use~~-~~ as claimed in claim 1721 wherein each protic acid is a hydrohalide acid.

1923. ~~A method~~The use~~-~~ as claimed in claim 1721 wherein the or each protic acid is selected from HCl; HBr; HNO_3; H_2SO_4.

2024. ~~A method~~The use~~-~~ as claimed in any one of claims 1 to 1620 wherein the or each protic acid is an organic acid.

2125. ~~A method~~The use~~-~~ as claimed in claim 2024 wherein the or each protic acid is selected from H_2CO_3; CH_3COOH; methanesulfonic acid, 1,2-ethanedisulfonic acid, ethansulfonic acid, naphthalenedisulfonic acid, p-toluenesulfonic acid.

2226. ~~A method~~The use as claimed in any one of claims 1 to 1620, or claim 2125 wherein the MT-containing compound is LMTM:



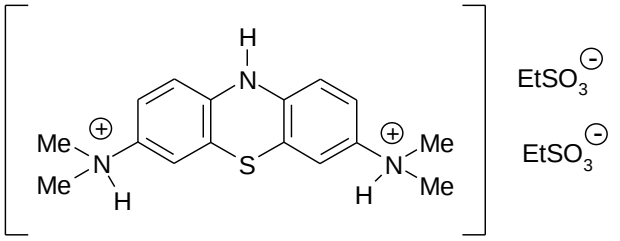
$MeSO_3^{\ominus}$

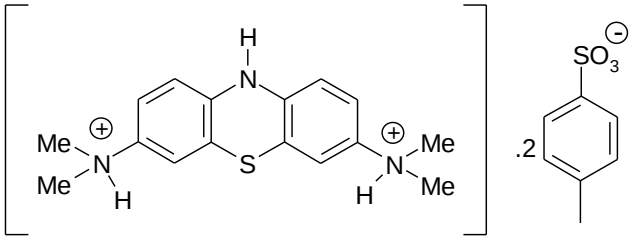
$MeSO_3^{\ominus}$

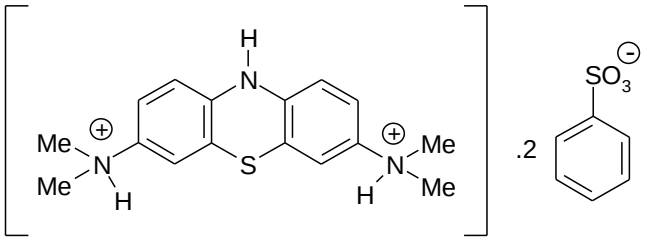
2327. ~~A method~~The use~~-~~ as claimed in claim 2226 wherein the total daily dose of LMTM is around 17~~–~~ mg/day.

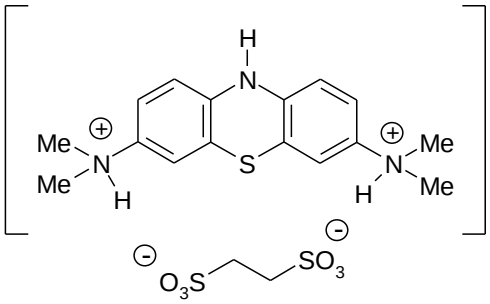
24~~28~~. ~~A method~~The use~~-~~ as claimed in claim 23~~27~~ wherein the dose of LMTM is about 27 mg/once per day.

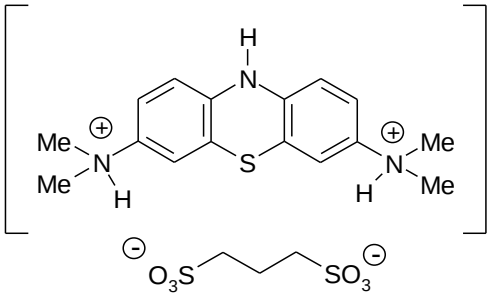
25~~29~~. ~~A method~~The use~~-~~ as claimed in any one of claims 1 to 12~~20~~ wherein the MT-containing compound is selected from the list consisting of:

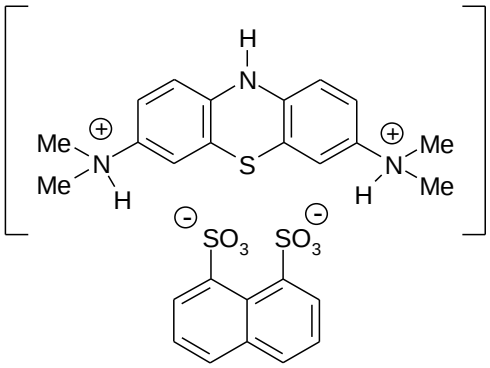












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~~30. An MT-containing compound as defined in any one of claims 1 to 29, for use in a method of treatment as defined in any one of claims 1 to 29.~~

~~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.~~