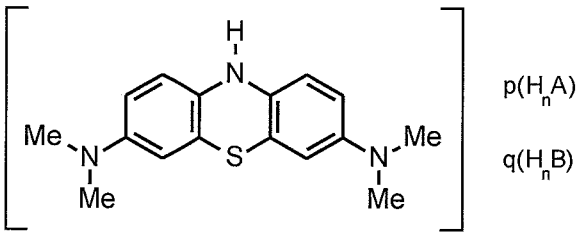
Claims

1 Use of an methylthioninium ("MT")-containing compound in the manufacture of a medicament for use in a method of therapeutic or prophylactic treatment of a neurodegenerative disorder of protein aggregation in a subject,

which method comprises orally administering to said subject said MT-containing compound,

wherein said administration provides a total daily dose of between 0.5 and 20mg of MT to the subject per day, optionally split into 2 or 3 doses,

wherein the compound is a compound of the following formula ("LMTX"):



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,

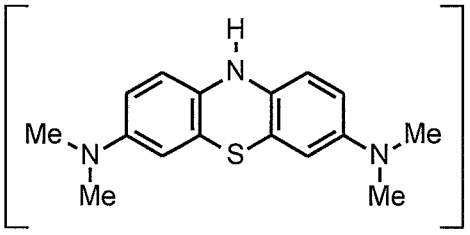
and wherein said neurodegenerative disorder is selected from the list consisting of: Alzheimer's disease; Pick's disease, progressive supranuclear palsy, frontotemporal dementia, FTD with parkinsonism linked to chromosome 17, frontotemporal lobar degeneration syndromes; disinhibition-dementia-parkinsonism-amyotrophy complex, pallido-ponto-nigral degeneration, Guam-ALS syndrome, pallido nigro luysian degeneration, cortico-basal degeneration, dementia with argyrophilic grains, dementia pugilistica or chronic traumatic encephalopathy, Down's syndrome, subacute sclerosing panencephalitis, Niemann-Pick disease, type C, Sanfilippo syndrome type B, or a

myotonic dystrophy DM1 or DM2; Huntington's disease, spinal bulbar muscular atrophy, dentatorubropallidoluysian atrophy or spinocerebellar ataxias; A TDP-43 proteinopathy which is FTLD-TDP ; Parkinson's disease, dementia with Lewy bodies and multiple system atrophy; Hereditary cerebral angiopathy; Amyotrophic lateral sclerosis; familial encephalopathy with neuronal inclusion bodies.

2 Use as claimed in claim 1 wherein the total daily dosage is 2 to 15 mg; or 3 to 10 mg.

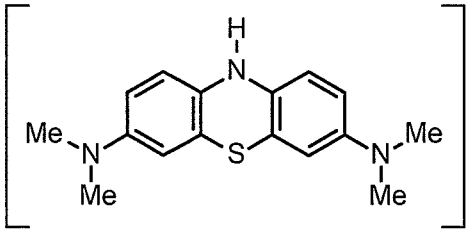
3 Use as claimed in claim 1 or claim 2 wherein:

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



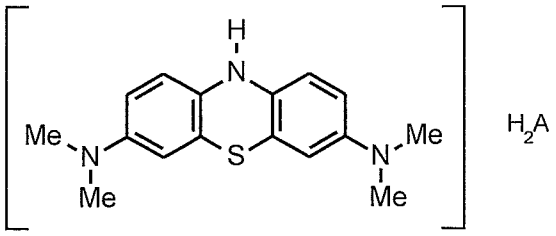
or

(b) the compound has the following formula:



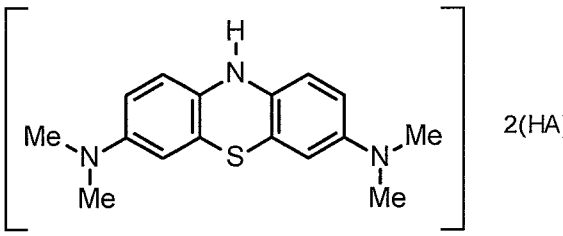
wherein each of H_nX is a protic acid, or

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



H_2A

4 Use as claimed in claim 3 wherein the compound has the following formula and is a bis-monoprotic acid:



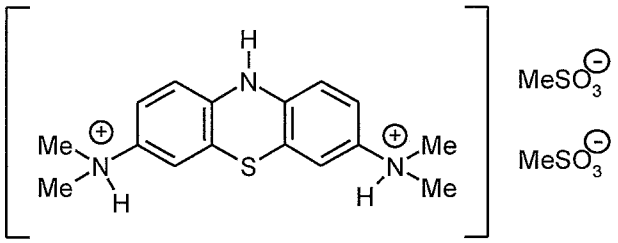
2(HA)

5 Use as claimed in any one of claims 1 to 4 wherein the or each protic acid is an inorganic acid.

6 Use as claimed in any one of claims 1 to 4 wherein the or each protic acid is an organic acid.

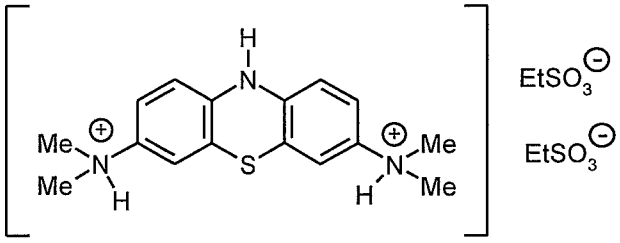
7 Use as claimed in claim 6 wherein the or each protic acid is selected from H_2CO_3; CH_3COOH; methanesulfonic acid, 1,2-ethanedisulfonic acid, ethansulfonic acid, naphthalenedisulfonic acid, p-toluenesulfonic acid.

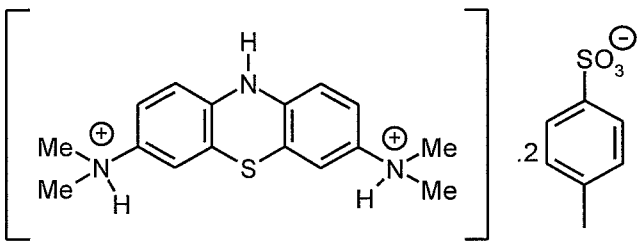
8 Use as claimed in claim 7 wherein the compound is LMTM:

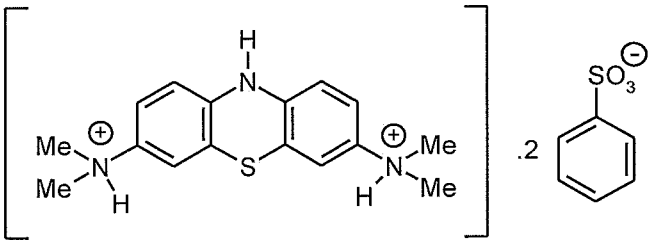


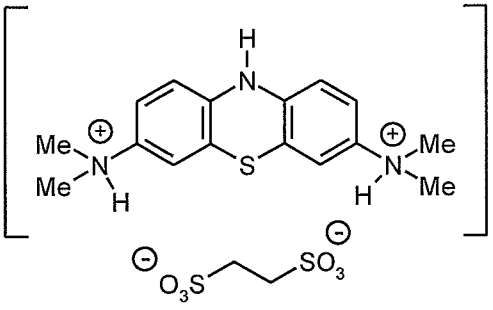
9 Use as claimed in claim 8 wherein the total daily dose of LMTM is around 0.8 to 33 mg/day, more preferably 6 to 12 mg/day of LMTM total.

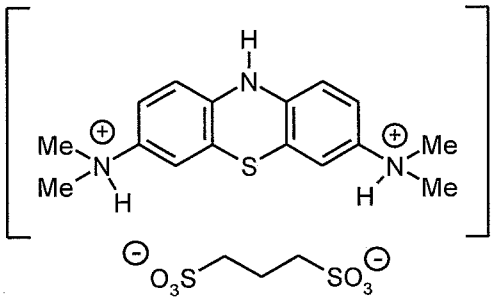
10 Use as claimed in claim 7 wherein the compound is selected from the list consisting of:

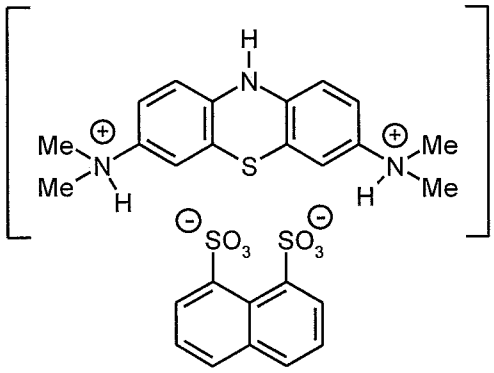












11 Use as claimed in any one of claims 1 to 10 wherein the subject has not historically received treatment with an acetylcholinesterase inhibitor or an N-methyl-D-aspartate receptor antagonist.

12 Use as claimed in any one of claims 1 to 10 wherein the subject has historically received treatment with an acetylcholinesterase inhibitor and\or an N-methyl-D-aspartate receptor antagonist, but ceased that medication at least 1, 2, 3, 4, 5, 6, 7, or 8 weeks prior to treatment with the MT containing compound.

13 Use as claimed in any one of claims 1 to 10 wherein the subject is selected as one who is receiving treatment with an acetylcholinesterase inhibitor and\or an N-methyl-D-aspartate receptor antagonist,

wherein said treatment with the acetylcholinesterase inhibitor and\or an N-methyl-D-aspartate receptor antagonist is discontinued prior to treatment with the MT containing compound.

14 A pharmaceutical composition comprising an MT compound as defined in any one of claims 1 to 10, and a pharmaceutically acceptable carrier or diluent, optionally in the form of a dosage unit, wherein the amount of MT in the composition or unit is 2 to 9 mg.

15 A nutraceutical composition comprising an MT compound as defined in any one of claims 1 to 10, and a nutrient compound, optionally in the form of a dosage unit or defined portion of a foodstuff, wherein the amount of MT in the unit is 0.5 to 10 mg, and wherein the nutrient is selected from the list consisting of: vitamin, micronutrient, antioxidant, herb, plant extract, seed extract, vegetable or fish oil, mineral, trace element, enzyme, or amino acid.

16 A composition as claimed in claim 15 which is selected from the list consisting of:

vitamin, which is optionally vitamin B_9, B_6 or B_{12}, vitamin C, vitamin E,

micronutrient and\or antioxidant, which is optionally a flavanol, flavonol, flavone, isoflavone, flavanone, anthocyanadin, non-flavonoid polyphenol, carotenoid, crocin, diterpene;

a herb or other plant extract, which is optionally *Ginkgo biloba, Hypericum perforatum*, *Piper methysticum*. *Valeriana officinalis*, *Bacopa monniera*, *Convolvulus pluricaulis*;

a plant oil or fish oil, which is optionally a ω-3 poyunsaturated fatty acid.

17 A composition as claimed in any one of claims 14 to 16 which is a tablet or capsule.

18 A composition as claimed in any one of claims 14 to 17 which comprises about any of: 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 7, 8, 9, 10, or 15 mg of LMTM.

19 Use of an MT-containing compound as defined in any one of claims 1 to 10 in the manufacture of a medicament for use in a method of therapeutic treatment of Alzheimer's disease (AD) in a subject,

which method comprises orally administering to said subject said MT-containing compound,

wherein said treatment does not include administration of either or both of an acetylcholinesterase inhibitor or an N-methyl-D-aspartate receptor antagonist.

20 Use as claimed in claim 19 wherein the subject has not historically received treatment with an acetylcholinesterase inhibitor or an N-methyl-D-aspartate receptor antagonist,

or wherein the subject has historically received treatment with an acetylcholinesterase inhibitor and\or an N-methyl-D-aspartate receptor antagonist, but ceased that medication at least 1, 2, 3, 4, 5, 6, 7, 8, week prior to treatment with the MT containing compound or wherein the subject is selected as one who is receiving treatment with an acetylcholinesterase inhibitor and\or an N-methyl-D-aspartate receptor antagonist,

wherein said treatment with the acetylcholinesterase inhibitor and\or an N-methyl-D-aspartate receptor antagonist is discontinued prior to treatment with the MT containing compound.