

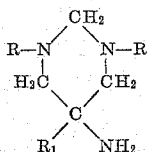
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3,072,529

**THERAPEUTIC COMPOSITION OF A 5-AMINO-
HEXAHYDRO-PYRIMIDINE AND SELECTED
CHELATING AGENTS**

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This invention relates to certain novel compositions of matter and relates more particularly to broad spectrum antibacterial and antifungal compositions comprising the combination of a chelating or sequestering agent with a 5-amino-hexahydro-pyrimidine compound of the formula



where in R is an alkyl, aryl, aralkyl, alkaryl, hydroxy-alkyl, aminoalkyl or cycloalkyl radical, and R₁ is hydrogen, a lower alkyl or hydroxymethyl radical. This invention is particularly concerned with the foregoing compositions wherein the chelating agents employed are those which are particularly adapted to remove or complex metals such as, for example, calcium, magnesium, iron, zinc, manganese and cobalt.

Recent studies have indicated that the 5-amino-hexahydro-pyrimidines having the general formula above are very useful antibacterial and antifungal agents. They are particularly valuable for topical application. Some indications of their value when they are employed systemically has also been observed. In using the 5-amino-hexahydro-pyrimidines for topical application both on the skin and on the mucous membranes of various body cavities, it is preferred for economic and other reasons, that as low an active concentration as possible be used. Topically applied compositions containing concentrations above about 0.5% by weight and especially above about 1.0% by weight have been found to be quite effective but in some instances, they have also been found to cause an undesirable degree of irritation. In addition, these higher concentrations frequently exert a local anesthetic action which tends to limit the usefulness of these compositions in the higher concentrations.

It is therefore, an important object of this invention to provide effective antibacterial and antifungal compositions comprising a 5-amino-hexahydro-pyrimidine of the above structure which are of greatly enhanced potency and which are effective both topically and systemically.

Another object of this invention is the preparation of antibacterial and antifungal compositions containing a 5-amino-hexahydro-pyrimidine wherein the effective concentration of the 5-amino-hexahydro-pyrimidine may be substantially decreased without any impairment in the antibacterial and antifungal potency of said compositions.

A further object of this invention is the provision of compositions containing a 5-amino-hexahydro-pyrimidine and a chelating or sequestering agent and which are highly active against a wide variety of microorganisms.

Other objects of this invention will appear from the following detailed description.

We have now found that the effective concentration of said 5-amino-hexahydro-pyrimidines in antibacterial and antifungal compositions may be substantially reduced without affecting the potency of said compositions if a chelating agent such as, for example ethylenediamine tetracetic acid, or any one or more of the several sodium and mixed sodium salts are employed in combination with the 5-amino-hexahydro-pyrimidine in said antibac-

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terial and antifungal compositions. By formulating these compositions in the manner described, only a fraction of the amount of the 5-amino-hexahydro-pyrimidine usually employed to obtain the desired antibacterial and antifungal activity is required. The novel compositions of our invention are particularly valuable in that they are active in preventing the growth of gram-negative microorganisms. This novel combination of active components is particularly effective in inhibiting and preventing the growth of the microorganism *Ps. aeruginosa* as well as actively inhibiting the growth of *P. vulgaris*, *E. coli* and *C. albicans*. While these microorganisms will exhibit growth in the presence of concentrations as high as 200 micrograms per milliliter of certain 5-amino-hexahydro-pyrimidines, by the addition of as little as 0.1 to 10% on the weight of the composition of a chelating agent, for example 0.1% by weight of ethylenediamine tetracetic acid, the growth of these organisms is completely inhibited in the presence of from only 1 to 10 micrograms per milliliter of the 5-amino-hexahydro-pyrimidine. Without impairing the marked activity of these compounds, the substantial reduction in concentration eliminates all possibility of irritation.

Examples of the 5-amino-hexahydro-pyrimidines which may be employed in forming the novel compositions of our invention are:

- 1,3-bismethyl-5-methyl-5-amino hexahydro-pyrimidine
- 1,3-bis (beta-ethylhexyl)-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bispropyl-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bis(isopropyl)-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bisbutyl-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bis (secondary butyl)-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bis (tertiary butyl)-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bis(hexyl)-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bisheptyl-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bis(octyl)-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bis(decyl)-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bis(dodecyl)-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bis(tetradecyl)-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bis(hexadecyl)-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bis (1-methylheptyl)-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bis (1,3-dimethylbutyl)-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bis (tertiary butyl-2-methyl)-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bis (isopropyl-2-methyl)-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bis (hydroxy tertiary butyl)-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bis (isopropyl)-5-hydroxymethyl-5-amino-hexahydro-pyrimidine
- 1,3-bis (B-hydroxyethylaminopropyl)-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bis (1,1-dimethyl-2-hydroxyethyl)-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bis (butylaminopropyl)-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bis (ethylhexyl)-5-amino-hexahydro-pyrimidine
- 1,3-bis (ethylhexyl)-5-hydroxymethyl-5-amino-hexahydro-pyrimidine
- 1,3-bis (cyclohexyl)-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bis (dicyclohexyl) - 5 - methyl-5-amino hexahydro-pyrimidine
- 1,3-bis(tolyl)-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bis(benzyl)-5-methyl-5-amino-hexahydro-pyrimidine

- 1,3-bis (methylbenzyl)-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bisphenyl-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bis (phenylethyl)-5-methyl-5-amino-hexahydro-pyrimidine
- 1,3-bis (ethylhexyl)-5-ethyl-5-amino-hexahydro-pyrimidine
- 1,3-bisdodecyl-5-ethyl-5-amino-hexahydro-pyrimidine
- 1,3-bis (hydroxy tertiary butyl)-5-ethyl-5-amino-hexahydro-pyrimidine
- 1,3-bis (cyclohexyl)-5-ethyl-5-amino-hexahydro-pyrimidine
- 1,3-bis (ethylhexyl)-5-propyl-5-amino-hexahydro-pyrimidine, and
- 1,3-bis (ethylhexyl)-5-butyl-5-amino-hexahydro-pyrimidine

In lieu of employing the 5-amino-hexahydro-pyrimidines above in the form of their free bases, the salts of these amine compounds may also be utilized. Salts are readily formed with acids such as, for example, acetic acid, phosphoric acid, hydrochloric acid, maleic acid, benzoic acid, citric acid, malic acid, oxalic acid, tartaric acid, succinic acid, glutaric acid, acetyl salicylic acid and salicylic acid, as well as perchloric acid, barbituric acid, sulfanilic acid, phitic acid and p-nitro benzoic acid. These amines also form useful salts with long chain aliphatic acid such as stearic acid, palmitic acid, oleic acid, myristic acid, and lauric acid.

The chelating agents which are most advantageously employed in combination with said 5-amino-hexahydro-pyrimidines are ethylenediamine tetraacetic acid and its several salts, for example, disodium ethylenediamine tetraacetic acid, trisodium ethylenediamine tetraacetic acid, tetrasodium ethylenediamine tetraacetic acid and disodium calcium ethylene-diamine tetraacetic acid. We have also found that diethylenetriamine pentaacetic acid and its sodium and calcium salts are also valuable in formulating our novel compositions. Uramil diacetic acid is another of the preferred chelating agents which are suitable for use in the compositions of our invention. Others which may be employed include N,N'-ethylene bis-(2-(2-hydroxyphenyl)) glycine. As stated, the chelating agents most useful are those which form chelates with Mg, Cu, Mn, Co, Fe, Zn and Ca.

In formulating the novel compositions of our invention we preferably employ a suitable pharmaceutical vehicle or carrier in which the necessary amounts of the active components are incorporated to yield a composition containing from 0.1 to 10% by weight of the chelating agent and from 0.01 to 0.5% by weight of the 5-amino-hexahydro-pyrimidine. The resulting compositions are highly effective on topical application against the organisms *Ps. aeruginosa*, *P. vulgaris*, *E. coli* and *C. albicans* and have been shown to be equally effective in controlling the growth of *Strep. hemolyticus*, *Lactobacillus casei*, *Micro-*

coccus pyogenes var. *aureus* and *Corynebacterium pyogenes*. The novel compositions of this invention find wide application in the treatment of various skin infections due to one or more of the organisms mentioned and are also effective treatment for various fungus infections of the scalp or the skin, for certain vaginal infections, as well as for many nose, throat and gingival infections due to the above and other bacteria and fungi.

Any conventional solid or liquid pharmaceutical vehicle or carrier may be employed in preparing these compositions. For topical application, the compositions may be formulated as an aqueous solution, a tincture, an ointment, a lotion, a salve, a cream, a gel, as a suppository or as an aqueous or non-aqueous spray. In dry, powdered form these compositions are also quite valuable for the treatment of fungus infections. Stable compositions are readily obtained with the usual carriers employed in pharmaceutical practice for the preparation of the dosage forms described above.

In order further to illustrate our invention but without being limited thereto, the following examples are given:

EXAMPLE I

2 parts by weight of 1,3-bis(beta-ethylhexyl)-5-methyl-5-amino-hexahydro-pyrimidine were dissolved in 1000 parts by weight of distilled water to form a 0.2% by weight aqueous solution. The solution obtained was divided and to one portion of this divided solution was added 2.5 parts by weight of ethylenediamine tetraacetic acid yielding a solution containing 0.2% by weight of said substituted hexahydro-pyrimidine and 0.5% by weight of ethylenediamine tetraacetic acid.

The comparative effect of these solutions on the skin flora of the human axilla was determined as follows:

Bacterial samples of the axilla were first obtained as a basis for comparison, by rotating a sterile cotton swab, presoaked in distilled water, over a prescribed skin area, placing the swab in 10 ml. of gelatin phosphate, and then culturing an aliquot of the sample on nutrient agar under aerobic and anaerobic conditions. The surviving bacterial colonies were counted and recorded and this count served as the baseline.

At zero time the right axilla received a single spray of 0.6 gram of the combined solution which is equal to an application of about 228 micrograms of the 1,3-bis(beta-ethylhexyl) - 5 - methyl-5-amino-hexahydro - pyrimidine. The left axilla received seven repeated sprays of the 0.2% solution (minus the ethylenediamine tetraacetic acid), the applications being allowed to dry between the separate sprays. A total application of about 1596 micrograms of 1,3 - bis(beta - ethylhexyl) - 5 - methyl - 5 - amino - hexahydro pyrimidine was thus made. Bacterial samples were taken at 1, 6 and 24 hours from each axilla and the samples cultured in the manner described, using BHI broth and nutrient agar for aerobic culture, and thioglycollate broth and BBL anaerobic agar for the anaerobic culture medium. The results obtained were as follows:

Table I

Time of sample hrs.	Axilla R. or L.	Ten fold dilutions of sample used	Aerobic number of colonies	Anaerobic number of colonies	Total count aerobic x 10 ³	Total count anaerobic x 10 ³
0	Right.....	5	35	46	3.5	4.5
	Left.....	5	39 81 114	45 134 103	9.7	11.8
1	Right.....	4	33 32	35 31	0.3	0.33
	Left.....	3	210 200	217 277	0.25	0.20
6	Right.....	4	126 96	-----	0.1	-----
	Left.....	4	219 259	-----	2.2	-----
24	Right.....	4	14 10	-----	0.1	-----
	Left.....	5	107 123	-----	11.0	-----

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EXAMPLE II

The following components are combined to form a composition suitable for nasal instillation.

Components:	Parts
1,3 - bis - (beta - ethylhexyl) - 5 - methyl - 5-amino hexahydropyrimidine -----gm--	1.0
Polyoxyethylene sorbitan mono-oleate (polysorbate 80) -----gm--	14.0
Chlorobutanol -----gm--	5.5
Sodium chloride -----gm--	8.0
Diethylene triamine pentaacetic acid -----gm--	5.0
Sodium hydroxide (10% solution, w./v.) -----cc--	15.0
Distilled water (q.s.) -----cc--	1000.0

The components are combined in the following manner:

The 1,3-bis(beta-ethylhexyl)-5-methyl-5-amino hexahydropyrimidine and polysorbate 80 are dissolved in 50 parts by weight of distilled water. The chlorobutanol and sodium chloride are separately dissolved in 850 parts by weight of distilled water heated to 80° C. and the diethylene triamine pentaacetic acid is dissolved in the sodium hydroxide solution. The separate solutions thus formed are combined and sufficient distilled water added to volume.

EXAMPLE III

An ointment is prepared from the following components.

Components:	Parts
1,3 - bis - (beta - ethylhexyl) - 5 - methyl - 5-amino hexahydropyrimidine -----gm--	1.0
Polysorbate 80 -----gm--	10.0
Polyethylene glycol (mol. wgt. about 400) -----gm--	500.0
Polyethylene glycol (mol. wgt. about 4000) -----gm--	400.0
Succinic acid -----gm--	0.4
Diethylene triamine pentaacetic acid -----gm--	5.0
Sodium hydroxide (10% solution, w./v.) -----cc--	15.0
Distilled water (q.s.) -----gm--	1000.0

To form the ointment preparation the 1,3-bis-beta-ethylhexyl)-5 - methyl-5 - amino - hexahydropyrimidine is dissolved in the polysorbate 80 and added to a previously melted mixture of the polyethylene glycols. A previously prepared solution of the succinic acid in 50 cc. of water is added followed by the addition of a solution of the diethylene triamine pentaacetic acid in the sodium hydroxide solution. After thorough mixing, the composition is adjusted to weight by the addition of water.

EXAMPLE IV

A shampoo preparation is formulated from the following components in the manner described.

Components:	Parts
1,3 - bis - (beta - ethylhexyl) - 5 - methyl - 5-amino hexahydropyrimidine -----gm--	1.0
Polyethylene glycol (mol. wgt. about 400) distearate -----gm--	16.7
Ammonium lauryl sulfate (27% solution) -----gm--	500.0
Diethylene triamine pentaacetic acid -----gm--	5.0
Sodium hydroxide (10% solution, w./v.) -----cc--	15.0
Distilled water -----cc--	20.0
Ethyl alcohol (q.s.) -----cc--	1000.0
Perfume (optional) -----cc--	1.8

The polyethylene glycol distearate is heated with 250 gm. of the ammonium lauryl sulfate solution until melted. There are then added, in order, the remainder of the am-

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monium lauryl sulfate solution, the 1,3-bis-(beta-ethylhexyl)-5-methyl-5-amino - hexahydropyrimidine dissolved in 100 cc. of the ethyl alcohol, the diethylene triamine pentaacetic acid dissolved in the sodium hydroxide solution, and the distilled water. The volume is adjusted to one liter with alcohol and the perfume added.

EXAMPLE V

A colloidal suspension suitable for therapeutic application is formed by combining the following components.

Components:	Parts
1,3 - bis - (beta - ethylhexyl) - 5 - methyl - 5-amino hexahydropyrimidine -----gm--	1.0
Hydrochloric acid, 10% (q.s., pH 2.0-2.5).	
Polyvinylpyrrolidone -----gm--	40.0
Sodium hydroxide, 30% solution (pH 6.8-7.2).	
Sodium carboxymethyl cellulose (Hercules 120 HV) -----gm--	20.0
Diethylene triamine pentaacetic acid -----gm--	50.0
Sodium hydroxide (10% solution, w./v.) -----cc--	150.0
Distilled water (q.s.) -----cc--	1000.0

In forming the suspension, the hydrochloric acid is added to the 1,3-bis(beta-ethylhexyl) - 5-methyl-5-amino-hexahydropyrimidine until a pH of 2.0-2.5 is reached, a solution of the polyvinylpyrrolidone in 40 cc. of distilled water is then added and the pH is adjusted to 6.8-7.2 with the sodium hydroxide solution. A previously prepared solution of the sodium carboxymethyl cellulose in 600 cc. of distilled water is added followed by a solution of the diethylene triamine pentaacetic acid in the 10% aqueous sodium hydroxide solution. The preparation is thoroughly mixed and adjusted to the indicated volume with distilled water.

EXAMPLE VI

A colloidal suspension is formed of the following.

Components:	Parts
1,3-bis (beta-ethylhexyl)-5-methyl-5-amino-hexahydro-pyrimidine -----gm--	5.0
Hydrochloric acid (10% aqueous solution)---	q.s.
Polyvinylpyrrolidone -----gm--	40.0
Sodium hydroxide (30% aqueous solution)---	q.s.
Sodium carboxymethyl cellulose (Hercules 70 HV)-----gm--	16.6
Polyethylene glycol (mol. wgt. about 400) -----gm--	41.6
Sodium chloride-----gm--	4.0
Sodium benzoate-----gm--	1.5
Ethylene diamine tetraacetic acid-----gm--	100.0
Distilled water (q.s.)-----gm--	1000.0

The hydrochloric acid solution is added to the 1,3-bis-(beta-ethylhexyl)-5-amino-hexahydro-pyrimidine until a pH of 2.0-2.5 is reached. To this mixture is then added a solution of the polyvinylpyrrolidone in 40 cc. of distilled water and the pH then adjusted to 6.8-7.2 by adding a sufficient amount of the sodium hydroxide solution. This mixture is then added to a previously prepared solution of the sodium carboxymethyl cellulose in 500 cc. of distilled water to which the polyethylene glycol, sodium chloride, and sodium benzoate have been added. To form the final suspension a solution of the ethylene diamine tetraacetic acid in sodium hydroxide solution is added, the volume is adjusted and the suspension formed is thoroughly mixed.

EXAMPLE VII

A stable emulsion is prepared from the following.

Components:	Parts
1,3-bis-(beta-ethylhexyl)-5-methyl-5-amino- hexahydro-primidine -----gm--	4.00
Brominated vegetable oil-----gm--	4.00
Methyl parahydroxybenzoate-----gm--	0.80
Propyl parahydroxybenzoate-----gm--	0.16
Polysorbate 80 -----gm--	8.00
Methyl cellulose (400 cps. viscosity) --gm--	8.00
Glyceryl monostearate, pure-----gm--	28.00
Diethylene triamine pentaacetic acid--gm--	50.00
Sodium hydroxide (10% solution w./v.)	cc-- 150.00
Distilled water (q.s.)-----cc--	1000.00

The glyceryl monostearate is heated to 70° C. and a mixture of the 1,3-bis-(beta-ethylhexyl)-5-methyl-5-amino-hexahydro-pyrimidine, brominated vegetable oil, and polysorbate 80 previously heated to 70° C. is added. The propyl parahydroxybenzoate is then dissolved in this melt and the mixture added to a solution of the methyl parahydroxybenzoate in 400 cc. of distilled water heated to 70° C. to which had been added the diethylene triamine pentaacetic acid in the aqueous sodium hydroxide solution. Stirring is continued while heating this portion of the batch to 90° C. and then stirring is continued until cooled to room temperature. The methyl cellulose is soaked in 125 cc. of distilled water at 90° C., mixed for about 30 minutes and then 125 cc. of distilled water, cooled to 4° C. is added slowly while mixing. The mixture obtained is stored at refrigerator temperature over night and, after the temperature is raised to room temperature, the latter is added to the 1,3-bis(beta-ethylhexyl)-5-methyl-5-amino-hexahydro-pyrimidine solution previously formed, the whole mixed well, and then adjusted to volume with distilled water.

EXAMPLE VIII

A suitable therapeutic ointment is formed from the following.

Components:	Parts
1,3 - bis(beta - ethylhexyl)-5-methyl-5-amino hexahydro-pyrimidine -----gm--	1.0
Polysorbate 80-----gm--	10.0
Polyethylene glycol (mol. wgt. about 400)	gm-- 500.0
Polyethylene glycol (mol. wgt. about 4000)	gm-- 400.00
Succinic acid-----gm--	0.4
Uramil diacetic acid-----gm--	5.0
Distilled water (q.s.)-----gm--	1000.0

The 1,3-bis-(beta-ethylhexyl)-5-methyl-5-amino hexahydro-pyrimidine is dissolved in the polysorbate 80 and added to a previously melted mixture of the polyethylene glycol. A previously prepared solution of the succinic acid in 50 cc. of water is then added. The uramil diacetic acid is triturated with about 10 gm. of the base material, the latter then mixed with the remainder of the base and the ointment formed is finally adjusted to weight with distilled water.

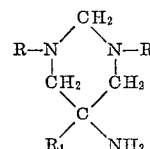
It is understood that the foregoing detailed description is given merely by way of illustration and that many variations may be made therein without departing from the spirit of my invention.

Having described our invention, what we desire to secure by Letters Patent is:

What we claim is:

1. A therapeutic composition comprising a pharmaceutical carrier, from 0.1 to 10% by weight of a chelating agent selected from the group consisting of ethylenediamine tetraacetic acid, diethylenetriamine pentaacetic acid, uramil diacetic acid, N,N'-ethylene bis [2-(2-hydroxyphenyl)] glycine and salts thereof and from 0.01 to

0.5% by weight of a member of the group consisting of a 5-amino-hexahydro-pyrimidine of the formula



wherein R is a radical of the group consisting of alkyl, aryl, aralkyl, alkaryl, hydroxyalkyl, aminoalkyl and cycloalkyl radicals and R₁ is selected from the group consisting of hydrogen, lower alkyl and hydroxymethyl, and the non-toxic salts of said 5-amino-hexahydro-pyrimidine.

2. A therapeutic composition as defined in claim 1 wherein the chelating agent is ethylenediamine tetraacetic acid.

3. A therapeutic composition as defined in claim 1, wherein the chelating agent is diethylenetriamine pentaacetic acid.

4. A therapeutic composition as defined in claim 1, wherein the chelating agent is uramil diacetic acid.

5. A therapeutic composition as defined in claim 1 wherein the chelating agent is disodium ethylenediamine tetraacetic acid.

6. A therapeutic composition as defined in claim 1, wherein the chelating agent is N,N'-ethylene bis-[2-(O-hydroxyphenyl)] glycine.

7. A therapeutic composition comprising a pharmaceutical carrier, from 0.1 to 10% by weight of ethylenediamine tetraacetic acid and from 0.01 to 0.5% by weight of a member of the group consisting of 1,3-bis (beta-ethylhexyl)-5-methyl-5-amino - hexahydro - pyrimidine, and the non-toxic salts thereof.

8. A therapeutic composition comprising a pharmaceutical carrier, from 0.1 to 10% by weight of diethylenetriamine pentaacetic acid and from 0.01 to 0.5% by weight of a member of the group consisting of 1,3-bis (beta-ethylhexyl)-5-methyl-5-amino-hexahydro-pyrimidine, and the non-toxic salts thereof.

9. A therapeutic composition comprising a pharmaceutical carrier, from 0.1 to 10% by weight of uramil diacetic acid and from 0.01 to 0.5% by weight of a member of the group consisting of 1,3-bis(beta-ethylhexyl)-5-methyl-5-amino-hexahydro-pyrimidine, and the non-toxic salts thereof.

10. A therapeutic composition comprising a pharmaceutical carrier, from 0.1 to 10% by weight of N,N'-ethylene bis-[2-(O-hydroxyphenyl)] glycine and from 0.01 to 0.5% by weight of a member of the group consisting of 1,3-bis(beta-ethylhexyl)-5-methyl-5 - amino - hexahydro-pyrimidine, and the non-toxic salts thereof.

11. A therapeutic composition comprising a pharmaceutical carrier, from 0.1 to 10% by weight of disodium ethylenediamine tetraacetic acid and from 0.01 to 0.5% by weight of a member of the group consisting of 1,3-bis (beta-ethylhexyl)-4-methyl-5-amino - hexahydro - pyrimidine, and the non-toxic salts thereof.

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