administration in combination with a second agent for treating fatty liver disease. In one aspect, there is provided use of a therapeutically effective amount of a cysteamine salt or cystamine salt in the manufacture of a medicament for treatment of non-alcoholic steatohepatitis (NASH) or non-alcoholic fatty liver disease (NAFLD), wherein the cysteamine salt or cystamine salt comprise enterically coated granules or tablets for oral administration. Also included is use of a second agent for treating fatty liver disease in preparation of a medicament for administration in combination with a cysteamine product. Further provided are kits comprising a cysteamine product for treatment of fatty liver disease, optionally with a second agent for treating fatty liver disease, and instructions for use in treatment of fatty liver disease. The term "fatty liver disease" may include or exclude NASH.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] Figure 1 shows the effect of cysteamine treatment at 0, 75 and 250 mg/kg/day, delivered intraperitoneally, on aspartate aminotransferase (AST) levels in animals fed a high fat diet (HFD) for 8 days. AST levels for control animals, not fed a HFD, are also shown. The graph depicts mean AST values from blood samples collected on study day-1 ("pre") and on study day 8 (SD8).

[0008] Figure 2 shows the effect of cysteamine treatment at 0, 75 and 250 mg/kg/day, delivered intraperitoneally, on cholesterol levels in animals fed a HFD for 8 days. Cholesterol levels for control animals, not fed a HFD, are also shown. The graph depicts mean cholesterol values from blood samples collected on study day-1 ("pre") and on study day 8 (SD8).

[0009] Figure 3 shows the effect of cysteamine treatment at 0, 75 and 250 mg/kg/day, delivered intraperitoneally, on low density lipoprotein-cholesterol (LDL-cholesterol) levels in animals fed a HFD for 8 days. LDL-cholesterol levels for control animals, not fed a HFD, are also shown. The graph depicts mean LDL-cholesterol values from blood samples collected on study day-1 ("pre") and on study day 8 (SD8).

WHAT IS CLAIMED:

1. Use of a therapeutically effective amount of a cysteamine salt or cystamine salt in the manufacture of a medicament for treatment of non-alcoholic steatohepatitis (NASH) or non-alcoholic fatty liver disease (NAFLD), wherein the cysteamine salt or cystamine salt comprise enterically coated granules or tablets for oral administration.

2. The use of claim 1, wherein the total daily dose of cysteamine salt or cystamine salt is 0.25-4.0 g/m^2 body surface.

3. The use of any of claims 1-2, wherein the medicament is to be administered at a frequency of 4 or less times per day.

4. The use of claim 3, wherein the medicament is to be administered two times per day.

5. The use of any of claims 1-4, wherein the medicament is a delayed or controlled release dosage form that provides increased delivery of the cysteamine salt or cystamine salt to the small intestine.

6. The use of claim 5, wherein the medicament provides a C_{max} of the cysteamine salt or cystamine salt that is at least about 35% higher than the C_{max} provided by an immediate release dosage form containing the same amount of the cysteamine salt or cystamine salt.

7. The use of claim 5, wherein the delayed or controlled release dosage form provides a C_{max} at least about 50% higher than the C_{max} of the immediate release dosage form.

8. The use of claim 5, wherein the delayed or controlled release dosage form provides a C_{max} up to about 75% higher than the C_{max} of the immediate release dosage form.

9. The use of claim 1, wherein the enteric coating is a composition selected from the group consisting of polymerized gelatin, shellac, methacrylic acid copolymer type C NF, cellulose butyrate phthalate, cellulose hydrogen phthalate, cellulose proprionate phthalate, polyvinyl acetate phthalate (PVAP), cellulose acetate phthalate (CAP), cellulose acetate trimellitate (CAT), hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate, dioxypropyl methylcellulose succinate, carboxymethyl ethylcellulose (CMEC) , hydroxypropyl methylcellulose acetate succinate (HPMCAS) , and acrylic acid polymers and copolymers, typically formed from methyl acrylate, ethyl acrylate, methyl methacrylate and/or ethyl methacrylate with copolymers of acrylic and methacrylic acid esters.

10. The use of any of the foregoing claims, wherein the medicament results in improvement in liver fibrosis compared to levels before administration of the cysteamine salt or cystamine salt.

11. The use of any of claims 1-9, wherein the medicament results in a reduction in fat content of liver.

12. The use of any of claims 1-9, wherein the medicament results in a reduction in the incidence of or progression of cirrhosis.

13. The use of any of claims 1-9, wherein the medicament results in a reduction in the incidence of hepatocellular carcinoma.

14. The use of any of claims 1-9, wherein the medicament results in a decrease in hepatic aminotransferase levels compared to levels before administration of the cysteamine salt or cystamine salt.

15. The use of any of claims 1-9, wherein the medicament results in a reduction in hepatic transaminase of between 10% to 40% compared to levels before treatment.

16. The use of any of claims 1-9, wherein the medicament results in a reduction in alanine anminotransferase levels in a treated patient to approximately 30%, 20% or 10% above normal ALT levels, or at normal ALT levels ($\geq$ 40 iu/L).

17. The use of any of claims 1-9, wherein the medicament results in a reduction in aspartate anminotransferase levels in a treated patient to approximately 30%, 20% or 10% above normal AST levels or to normal AST levels.

18. The use of any of claims 1-9, wherein the medicament results in a reduction in serum ferritin levels compared to levels before treatment with the cysteamine salt or cystamine salt.

19. The use of any of claims 1-9, wherein the cysteamine salt or cystamine salt is to be administered with a second agent useful to treat fatty liver disease.

20. The use of any of claims 1-19, wherein the patient is a child or adolescent.