CLAIMS

1. Use of a fixed dosage apolipoprotein formulation for the preparation of a medicament for prophylactically or therapeutically treating cardiovascular disease, hypercholesterolaemia or hypocholesterolaemia in a human with a body weight in the body weight range 60-140 kg, wherein the apolipoprotein formulation has been determined to display relatively reduced inter-patient variability in exposure to the apolipoprotein of the formulation compared to that which would be observed or associated with a weight-adjusted dosage regime.

2. The use according to Claim 1, wherein the cardiovascular disease, hypercholesterolaemia or hypocholesterolaemia includes acute coronary syndrome (ACS), atherosclerosis, unstable angina pectoris, and myocardial infarction.

3. The use according to Claim 1 or 2, wherein the inter-patient variability in exposure to apolipoprotein is less than 90% of that observed or associated with the weight-adjusted dosage regime.

4. The use of any one of Claims 1-3, wherein the fixed dosage comprises an amount of apolipoprotein in a range selected from: 0.1-15g; 1-10g; 2-9g; 3-8g; 4-7g; and 5-6g of apolipoprotein.

5. The use according to Claim 9, wherein the fixed dosage comprises 0.25g, 0.5g, 1g, 1.7g, 2g, 3.4g, 4g, 5.1g, 6g, 6.8g or 8g apolipoprotein.

6. The use according to any one of Claims 1-5, wherein the apolipoprotein is Apo-A1 or a fragment thereof.

7. The use according to any one of Claims 1-6, wherein the apolipoprotein formulation is a reconstituted high density apolipoprotein (rHDL) formulation.

8. The use according to Claim 7, wherein the rHDL formulation comprises the apolipoprotein, one or more lipids and optionally a detergent.

9. The use according to Claim 8, wherein the apolipoprotein is Apo A-I purified from plasma, the lipid is phosphatidylcholine, and the rHDL formulation further comprises sodium cholate detergent.

10. The use according to Claim 9, wherein the ratio between the apolipoprotein and the lipid is from 1:40 to 1:75 (mol:mol), and the sodium cholate is present at a concentration of 0.5 to 0.9 g/L.

11. The use according to Claim 8, wherein the apolipoprotein is recombinant Apo A-I and the one or more lipids is a mixture of sphingomyelin and phosphatidylglycerol.

12. The use according to Claim 11, wherein the ratio between the apolipoprotein and the lipid is between 1:80 and 1:120 (mol:mol) and the sphingomyelin and the phosphatidylglycerol are present in a ratio from 90:10 to 99:1 (w:w).

13. A method of producing a fixed dosage apolipoprotein formulation comprising an apolipoprotein or a fragment thereof, including the step of producing the apolipoprotein formulation at a fixed dosage which is therapeutically effective upon administration to a human body of a body weight in the body weight range of 60-140 kg and to display relatively reduced inter-patient variability in exposure to the apolipoprotein constituent of the formulation compared to that which would be observed or associate with a weight-adjusted dosage.

14. An apolipoprotein formulation, comprising an apolipoprotein or a fragment thereof at a fixed dosage which is therapeutically effective upon administration to a human of a body weight in the body weight range of 60-140 kg; wherein the apolipoprotein formulation displays relatively reduced inter-patient variability in exposure to the apolipoprotein constituent of the formulation compared to that which would be observed or associated with a weight-adjusted dosage regime.

15. The apolipoprotein formulation of Claim 14, wherein the variability is less than 90% of that observed or associated with the weight-adjusted dosage regime.

16. The apolipoprotein formulation according to Claim 14 or 15, wherein the fixed dosage comprises an amount of apolipoptotein in a range selected from: 0.1-15g; 1-10g; 2-9g; 3-8g; 4-7g; and 5-6g apolipoprotein.

17. The apolipoprotein formulation of Claim 16, wherein the fixed dosage comprises an amount of apolipoprotein selected from: 0.25g; 0.5g; 1g; 1.7g; 2g; 3.4g; 4g; 5.1g; 6g; 6.8g; and 8g apolipoprotein.

18. The apolipoprotein formulation according to any one of Claims 14-17, wherein the apolipoprotein is Apo-A1 or a fragment thereof.

19. The apolipoprotein formulation according to any one of Claims 14-18, wherein the apolipoprotein formulation is a reconstituted high density lipoprotein (rHDL) formulation.

20. The apolipoprotein formulation according to Claim 19, wherein the rHDL formulation comprises the apolipoprotein, one or more lipids and optionally a detergent.

21. The apolipoprotein formulation according to Claim 20, wherein the rHDL formulation the apolipoprotein is Apo A-I purified from plasma, the lipid is phosphatidylcholine, and the rHDL formulation further comprises sodium cholate detergent.

22. The apolipoprotein formulation according to Claim 21, wherein the ratio between the apolipoprotein and the lipid is from 1:40 to 1:75 (mol:mol), and the sodium cholate is present at a concentration of 0.5 to 0.9 g/L.

23. The apolipoprotein formulation according to Claim 20, wherein the apolipoprotein is recombinant Apo A-I and the one or more lipids is a mixture of sphingomyelin and phosphatidylglycerol.

24. The apolipoprotein formulation according to Claim 23, wherein the ratio between the apolipoprotein and the lipid is between 1:80 and 1:120 (mol:mol) and the sphingomyelin and the phosphatidylglycerol are present in a ratio from 90:10 to 99:1 (w:w).

25. A kit comprising one or more unit doses of a fixed dosage apolipoprotein formulation according to any one of Claims 14-24; and one or more other kit components.

26. The kit of Claim 25, wherein said one or more other kit components include instructions for use; vials, containers or other storage vessels containing each of the unit doses; one or more delivery devices such as needles, catheters, syringes, tubing and the like; and/or packaging suitable for safely and conveniently storing and/or transporting the kit.

27. The kit of Claim 25 or 26, for use in therapeutically or prophylactically treating cardiovascular disease, hypercholesterolaemia or hypocholesterolaemia.

28. The kit of Claim 26, wherein the cardiovascular disease, hypercholesterolaemia or hypocholesterolaemia includes acute coronary

syndrome (ACS), atherosclerosis, unstable angina pectoris, and myocardial infarction.

CLAIMS

1. A method of producing a fixed dosage apolipoprotein formulation comprising an apolipoprotein or a fragment thereof, including the step of producing the apolipoprotein formulation at a fixed dosage which is therapeutically effective upon administration to a human in the body weight range 60-140 kg and to display relatively reduced inter-patient variability in exposure to the apolipoprotein constituent of the formulation compared to that which would be observed or associated with a weight-adjusted dosage.

2. A fixed dosage apolipoprotein formulation produced according to the method of Claim 1.

3. The fixed dosage apolipoprotein formulation of Claim 2, wherein the variability is less than 90% of that of that observed or associated with the weight-adjusted dosage regime.

4. The fixed dosage apolipoprotein formulation according to Claim 2 or Claim 3, wherein the fixed dosage comprises an amount of apolipoptotein in a range selected from: 0.1-15g; 1-10g; 2-9g; 3-8g; 4-7g; and 5-6g apolipoprotein.

5. The fixed dosage apolipoprotein formulation of Claim 4, wherein the fixed dosage comprises an amount of apolipoprotein selected from: 0.25g; 0.5g; 1g; 1.7g; 2g; 3.4g; 4g; 5.1g; 6g; 6.8g; and 8g apolipoprotein.

6. A fixed dosage apolipoprotein formulation, for use in prophylactically or therapeutically treating a disease, disorder or condition in a human wherein the fixed dosage apolipoprotein formulation is therapeutically effective upon administration to a human in the body weight range 60-140 kg and which displays relatively reduced inter-patient variability in exposure to the apolipoprotein constituent of the formulation compared to that which would be observed or associated with a weight-adjusted dosage, wherein the fixed dosage comprises an amount of apolipoptotein in a range 0.1-0.5g .

7. The fixed dosage apolipoprotein formulation of Claim 6, wherein the fixed dosage comprises an amount of apolipoprotein selected from: 0.25g; and 0.5g apolipoprotein.

8. The fixed dosage apolipoprotein formulation according to any one of Claims 15-20, wherein the apolipoprotein is Apo-A1 or a fragment thereof.

9. The fixed apolipoprotein formulation according to any one of Claims 2-8, wherein the apolipoprotein formulation is a reconstituted high density lipoprotein (rHDL) formulation.

10. The fixed dosage apolipoprotein formulation according to Claim 9, wherein in the rHDL formulation comprises the apolipoprotein, one or more lipids and optionally a detergent.

11. The fixed dosage apolipoprotein formulation according to Claim 10, wherein in the rHDL formulation the apolipoprotein is Apo A-I purified from plasma, the lipid is phosphatidylcholine, and the rHDL formulation further comprises sodium cholate detergent.

12. The fixed apolipoprotein formulation according to Claim 11, wherein the ratio between the apolipoprotein and the lipid is is from 1:40 to 1:75 (mol:mol), and the sodium cholate is present at a concentration of 0.5 to 0.9 g/L.

13. The fixed dosage apolipoprotein formulation according to Claim 12, wherein the apolipoprotein is recombinant Apo A-I and the one or more lipids is a mixture of sphingomyelin and phosphatidylglycerol.

14. The fixed dosage apolipoprotein formulation according to Claim 13, wherein the ratio between the apolipoprotein and the lipid is between 1:80 and 1:120 (mol:mol) and the sphingomyelin and the phosphatidylglycerol are present in a ratio from 90:10 to 99:1 (w:w).

15. A kit comprising one or more unit doses of a fixed dosage apolipoprotein formulation according to any one of Claims 2-14; and one or more other kit components.

16. The kit of Claim 15, wherein said one or more other kit components include instructions for use; vials, containers or other storage vessels containing each of the unit doses; one or more delivery devices such as needles, catheters, syringes, tubing and the like; and/or packaging suitable for safely and conveniently storing and/or transporting the kit.

17. The kit of Claim 15 or Claim 16, for use in therapeutically or prophylactically treating a disease, disorder or condition including cardiovascular disease, hypercholesterolaemia or hypocholesterolaemia.

18. The kit of Claim 17, wherein the disease, disorder or condition includes acute coronary syndrome (ACS), atherosclerosis, unstable angina pectoris, and myocardial infarction.

19. Use of an apolipoprotein in the manufacture of a fixed dosage apolipoprotein formulation for prophylactically or therapeutically treating a disease, disorder or condition in a human wherein the fixed dosage apolipoprotein formulation is therapeutically effective upon administration to a human in the body weight range 60-140 kg and has been determined to display relatively reduced inter-patient variability in exposure to the apolipoprotein constituent of the formulation compared to that which would be observed or associated with a weight-adjusted dosage.

20. The method of Claim 1, the fixed dosage formulation of any one of Claims 2-14 or the kit of any one of Claims 15-18, wherein the body weight range is 60-120 kg.

21. The method, the fixed dosage formulation or the kit of Claim 20, wherein the body weight range is 70-100 kg.

22. The method, the fixed dosage formulation or the kit of Claim 21, wherein the body weight range is 80-90 kg.