Claims

1. Use of a composition in the manufacture of a medicament for treating, ameliorating and/or preventing colorectal cancer (CRC) in humans, comprising administration of between 800 grams and 2365 grams of PEG or PEG block co-polymer over a period of 18 to 36 consecutive calendar months.

2. The use of claim 1, wherein administration is over a period of 24 consecutive calendar months or over a period of 36 consecutive calendar months.

3. The use of claim 1 or claim 2 comprising administration of between 0.1 grams and 6.0 grams of PEG or PEG block co-polymer on a daily basis.

4. The use of any one of the preceding claim for treating CRC in humans.

5. The use of any one of claims 1 to 3 for ameliorating CRC in humans by reducing the incidence and/or growth of aberrant crypt foci (ACF).

6. The use of any one of claims 1 to 3 for preventing CRC in humans.

7. The use of any one of the preceding claims for treating, ameliorating and/or preventing CRC in humans and for preventing constipation and/or maintaining normal gastrointestinal transit time in humans.

8. The use of any one of the preceding claims wherein the method comprises administration of between 266 and 1181 grams, or between 400.3 and 787.5 grams, of PEG or PEG block co-polymer over a period of 12 consecutive calendar months.

9. The use of any one of the preceding claims wherein the method comprises administration of between 22 and 98 grams of PEG or PEG block co-polymer over a period of one month.

10. The use of any one of the preceding claims comprising administration of between 5.1 and 22.7 grams of PEG or PEG block co-polymer over a period of one week.

11. The use of any one of the preceding claims comprising administration of between 0.73 and 3.22 grams of PEG or PEG block co-polymer over a period of one day.

12. The use of any one of the preceding claims comprising between 0.2 to 6.4 grams of PEG or PEG block co-polymer.

13. The use of any one of the preceding claims comprising between 3.0 to 5.0 grams of PEG or PEG block co-polymer.

14. The use of any one of the preceding claims comprising between 1.0 to 4.0 grams of PEG or PEG block co-polymer.

15. The use of claim 14 comprising between 1.5 and 2.5 grams of PEG or PEG block co-polymer.

16. The use of claim 15 comprising between 2.0 and 2.5 grams of PEG or PEG block co-polymer.

17. The use of claim 16 comprising 2.2 grams or thereabout of PEG or PEG block co-polymer.

18. The use of any one of claims 12 to 17 wherein the PEG or PEG block co-polymer is to be administered daily over a period of 24 or 36 consecutive calendar months.

19. The use of any one of claims 12 to 17, wherein the PEG or PEG block co-polymer is to be administered intermittently over a period of 24 or 36 consecutive calendar months.

20. The use of any one of the preceding claims wherein the PEG has an average molecular weight of between 1000 and 8000 Daltons.

21. The use of claim 20 wherein the PEG has an average molecular weight of between 3000 and 8000 Daltons.

22. The use of claim 21 wherein the PEG has an average molecular weight selected from the group consisting of 3350, 4000, 6000 and 8000 Daltons.

23. The use of claim 22 wherein the PEG is selected from the group consisting of macrogol 3350, macrogol 4000, macrogol 6000 and macrogol 8000.

24. The use of any one of the preceding claims wherein the human is predisposed towards developing CRC.

25. The use of claim 24, wherein the human is predisposed towards developing CRC based on any of the following: due to familial history and/or medical history, selected from a group consisting of a prior episode of CRC, colon polyps, Lynch's syndrome, and familial polyposis and/or health status and/or lifestyle.

26. The use of any one of the preceding claims wherein the human is aged 50 years or greater, or 55 years or greater, or 60 years or greater, or 60 to 75 years, or 65 to 75 years.

27. The use of any one of the preceding claims in oral dosage form.

28. The use of any one of the preceding claims wherein the composition is in the form of any one of the following: a tablet, capsule, caplet, troche, powder, granules, or liquid.

29. Use of a composition in the manufacture of a medicament for treating, ameliorating and/or preventing CRC in humans wherein the composition comprises the following components:

(a) 50 – 90 % w/w polyethylene glycol (PEG), having an average molecular weight within the range 2,000 to 10,000 Da; and

(b) 10 – 40 % w/w of a solid, wherein the solid is selected from the group consisting of sorbitol, lactose, lactose and starch, dextrates, cellulose, xylitol, maltitol and mannitol;

(c) optionally further excipients selected from the group consisting of flavourings, sweeteners and lubricants

30. The use according to claim 29 wherein the composition is a solid composition for oral administration as a solid.

31. The use of claim 29 or 30 wherein the composition is in the form of any one of the following: a tablet, a chewable, or suckable tablet.

32. The use of any one of claims 29 to 31 wherein the composition comprises 82 to 84 % w/w PEG.

33. The use of any one of claims 29 to 32 wherein the composition comprises 10 to 20 % w/w of component (b).

34. The use of claim 33 wherein the component (b) is mannitol, or granular mannitol.

35. The use of any one of claims 29 to 34 wherein the PEG has an average molecular weight of between 3000 and 4000 Da.

36. The use of any one of claims 29 to 35 wherein the composition comprises:

(a) 70 – 90 % w/w polyethylene glycol (PEG) having an average molecular weight within the range of 2,000 to 10,000 Da;

(b) 10 – 20 % w/w of the solid;

(c) 0 – 2.0% w/w lubricant; and

(d) 0 – 2.0% w/w flavouring.

37. The use of claim 36, wherein the composition comprises PEG and mannitol in a weight ratio of PEG:mannitol of 3:1 to 9:1.

38. The use of any one of claims 29 to 37 wherein the composition comprises a lubricant in an amount of 2.0% w/w or less, or 0.2 to 0.8% w/w, or 0.5% w/w.

39. The use as claimed in claim 38 wherein the lubricant is magnesium stearate.

40. The use of any one of claims 29 to 39 wherein the composition comprises a flavouring.

41. The use as claimed in claim 40 wherein the flavouring is peppermint, or raspberry-lemon.

42. The use of claim 41, wherein the peppermint is present at a level of 0.1 to 1 % w/w, or 0.4% w/w, or wherein the raspberry-lemon is present at a level of 0.5 to 2 % w/w, or 1.5% w/w.

43. The use of any one of claims 29 to 42 wherein the composition has a mass of 0.5 to 10g, or 1.0 to 5.0g.

44. The use as claimed in any one of claims 29 to 43 wherein the composition has a mass of 2.0 to 3.5g and comprises:
(a) 1.00 – 3.15g polyethylene glycol (PEG) having an average molecular weight within the range 2,000 to 10,000;
(b) 0.20 – 1.40g mannitol.

45. The use according to any one of claims 1 to 28 wherein the composition comprises the features described in any one of claims 29 to 44.

46. The use according to any one of the preceding claims wherein the compositions comprises a PEG block co-polymer.

47. Use of a composition comprising PEG or PEG block co-polymer in the manufacture of a medicament for treating, ameliorating and/or preventing CRC in humans, comprising administration of between 1.5 to 2.5 grams of PEG or PEG block co-polymer on a daily basis, wherein approximately 800 grams or greater of PEG or PEG block co-polymer is to be administered over a period of 24 or 36 consecutive calendar months.

Claims

1. A composition for use in a method for treating, ameliorating and/or preventing CRC in humans wherein the method comprises administering approximately 800 grams or greater (such as between 800 grams and 2365 grams) of PEG or PEG block co-polymer over a period of 36 consecutive calendar months.

2. A composition for use in a method for treating, ameliorating and/or preventing CRC in humans wherein the method comprises administering approximately 800 grams or greater (such as between 800 grams and 2365 grams) of PEG or PEG block co-polymer over a period of 24 consecutive calendar months.

3. A composition for use in a method for treating, ameliorating and/or preventing CRC in humans wherein the method comprises administering approximately 800 grams or greater (such as between 800 grams and 2365 grams) of PEG or PEG block co-polymer over a period of 18 to 36 consecutive calendar months.

4. A composition for use in a method for treating, ameliorating and/or preventing CRC in humans wherein the method comprises administering between 0.1 grams and 6.0 grams of PEG or PEG block co-polymer on a daily basis.

5. The composition of any preceding claim for treating CRC in humans.

6. The composition of any one of claims 1 to 4 for ameliorating CRC in humans (by e.g. reducing the incidence and/or growth of aberrant crypt foci (ACF)).

7. The composition of any one of claims 1 to 4 for preventing CRC in humans.

8. The composition of any preceding claim for treating, ameliorating and/or preventing CRC in humans and for the simultaneous use in preventing constipation and/or maintaining normal gastrointestinal transit time in humans.

9. The composition of any preceding claim wherein the method comprises administering between 266 and 1181 grams (e.g. between 400.3 to 1181.3 grams

or between 266.9 and 787.5 grams or 400.3 and 787.5 grams) of PEG or block co-polymer over a period of 12 consecutive calendar months.

10. The composition of any preceding claim wherein the method comprises administering between 22 and 98 grams (e.g. between 33.3 to 98.4 grams or between 22.2 and 65.6 grams or 65.6 grams and 98.4 grams) of PEG or PEG block co-polymer over a period of one month.

11. The composition of any preceding claim wherein the method comprises administering between 5.1 and 22.7 grams (e.g. between 7.7 to 22.7 grams or between 5.1 and 15.1 grams or between 15.1 and 22.7 grams) of PEG or PEG block co-polymer over a period of one week.

12. The composition of any preceding claim wherein the method comprises administering between 0.73 and 3.22 grams (e.g. between 1.1 to 3.2 grams or between 0.73 and 2.2 grams; or 2.2 to 3.2 grams) of PEG or PEG block co-polymer over a period of one day.

13. The composition of any preceding claim comprising between 0.2 to 6.4 grams of PEG or PEG block co-polymer.

14. The composition of any preceding claim comprising between 3.0 to 5.0 grams of PEG or PEG block co-polymer.

15. The composition of any preceding claim comprising between 1.0 to 4.0 grams of PEG or PEG block co-polymer.

16. The composition of claim 15 comprising between 1.5 and 2.5 grams of PEG or PEG block co-polymer.

17. The composition of claim 16 comprising between 2.0 and 2.5 grams of PEG or PEG block co-polymer.

18. The composition of claim 17 comprising 2.2 grams or thereabout of PEG or PEG block co-polymer.

19. The composition of any one of claims 13 to 18 which is administered daily over a period of 24 or 36 consecutive calendar months.

20. The composition of any one of claims 13 to 18 which is administered intermittently over a period of 24 or 36 consecutive calendar months.

21. The composition of any preceding claim wherein the PEG has an average molecular weight of between 1000 and 8000 Daltons.

22. The composition of claim 21 wherein the PEG has an average molecular weight of between 3000 and 8000 Daltons.

23. The composition of claim 22 wherein the PEG has an average molecular weight selected from the group consisting of; 3350, 4000, 6000, 8000 Daltons.

24. The composition of claim 23 wherein the PEG is selected from the group consisting of macrogol 3350, macrogol 4000, macrogol 6000, macrogol 8000.

25. The composition of any preceding claim wherein the human is predisposed towards developing CRC (e.g. due to familial history and/or medical history such as a prior episode of CRC or colon polyps, Lynch's syndrome, familial polyposis and/or health status and/or lifestyle).

26. The composition of any preceding claim wherein the human is aged 50 years or greater e.g. 55 years or greater such as 60 years or greater e.g. 60 to 75 years or 65 to 75 years.

27. The composition of any preceding claim in oral dosage form.

28. The composition of any preceding claim wherein the composition is in the form of a tablet, capsule, caplet, troche, powder, granules, liquid.

29. A composition for use in a method for treating, ameliorating and/or preventing CRC in humans which comprises:
(a) 50 – 90 % w/w polyethylene glycol (PEG), having an average molecular weight within the range 2,000 to 10,000 Da; and
(b) 10 – 40 % w/w of a solid;
(c) optionally further excipients such as flavourings, sweeteners and lubricants

30. The composition according to claim 29 which is a solid composition for oral administration as a solid.

31. The composition of claim 29 or 30 wherein the composition is in the form of a tablet (such as a chewable or suckable tablet).

32. The composition of any one of claims 29 to 31 wherein the solid of component (b) is selected from the group; sorbitol, lactose, lactose and starch (e.g. a compound comprising lactose monohydrate and maize starch such as Starlac®) dextrates, cellulose, xylitol, maltitol and mannitol.

33. The composition of any one of claims 29 to 32 comprising 82 to 84 % w/w PEG.

34. The composition of any one of claims 29 to 33 comprising 10 to 20 % w/w of solid of component (b).

35. The composition of claim 34 wherein the solid of component (b) is mannitol, for example granular mannitol.

36. The composition of any one of claims 29 to 35 wherein the PEG has an average molecular weight of between 3000 and 4000 Da.

37. The composition of any one of claims 29 to 36 comprising:
(a) 70 – 90 % w/w polyethylene glycol (PEG) having an average molecular weight within the range 2,000 to 10,000 Da;

(b) 10 – 20 % w/w of the solid such as mannitol;

(c) 0 – 2.0% w/w lubricant; and

(d) 0 – 2.0% w/w flavouring.

38. The composition of claim 37, comprising PEG and mannitol in a weight ratio of PEG: mannitol of 3:1 to 9:1.

39. The composition of any one of claims 29 to 38 comprising a lubricant in an amount of 2.0% w/w or less, for example 0.2 to 0.8% w/w, for example 0.5% w/w.

40. The composition as claimed in claim 39 wherein the lubricant is magnesium stearate.

41. The composition of any one of claims 29 to 40 comprising a flavouring.

42. The composition as claimed in claim 41 wherein the flavouring is peppermint, preferably present at a level of 0.1 to 1 % w/w (e.g. 0.4% w/w), or raspberry-lemon, preferably present at a level of 0.5 to 2% w/w (e.g. (1.5% w/w).

43. The composition of any one of claims 29 to 42 that is substantially free from electrolytes (e.g. sodium chloride, potassium chloride, bicarbonates such as sodium bicarbonate, sulphates such as sodium sulphate or phosphates).

44. The composition of any one of claims 29 to 43 that has a mass of 0.5 to 10g, for example 1.0 to 5.0g.

45. The composition as claimed in any one of claims 29 to 44 that has a mass of 2.0 to 3.5g and comprises:

(a) 1.00 – 3.15g polyethylene glycol (PEG) having an average molecular weight within the range 2,000 to 10,000;

(b) 0.20 – 1.40g mannitol.

46. The composition as claimed in claim 29 which is is a composition substantially as described herein with reference to any one of Examples 2 to 6.

47. The composition according to any one of claims 29 to 46 for use in a method according to any one of claims 1 to 28.

48. A kit comprising a plurality of units of the composition of any one of claims 29 to 47 together with directions for use.

49. A method of or for treating, ameliorating and/or preventing CRC in humans according to the method of any one of claims 1 to 28.

50. The method of claim 49 which comprises administrating the composition according to any one of claims 29 to 47.

51. A composition or method according to any preceding claim wherein the composition or method comprises a PEG block co-polymer such as Pluronic® F68.