WHAT IS CLAIMED IS:

1. A method for treating a luteal phase defect in a patient in need thereof, the method comprising administering to the patient a monolithic intravaginal ring comprising:

(a) a therapeutically effective amount of progesterone;

(b) a polysiloxane elastomer; and

(c) a pharmaceutically acceptable hydrocarbon or glycerol esters of a fatty acid,

wherein the polysiloxane elastomer is present in a concentration of about 55% to about 90% by total weight of the ring.

2. The method of claim 1, wherein the progesterone is homogeneously dispersed in the polysiloxane elastomer.

3. The method of claim 1, wherein the polysiloxane elastomer is a diorganopolysiloxane elastomer.

4. The method of claim 3, wherein the diorganopolysiloxane elastomer is dimethylpolysiloxane elastomer.

5. The method of claim 4, wherein the dimethylpolysiloxane elastomer further comprises a dimethylmethylhydrogen polysiloxane crosslink.

6. The method of claim 1, wherein the pharmaceutically acceptable hydrocarbon or glycerol esters of a fatty acid is present in a concentration of about 0.1% to about 10% by total weight of the ring.

7. The method of claim 1, wherein the progesterone is present in a concentration of about 15% to about 30% by total weight of the ring.

8. The method of claim 1, wherein the progesterone is released at a steady rate for about 1 day to about 14 days.

9. The method of claim 1, wherein the progesterone is released at a steady rate for about 1 day to about 10 days.

10. The method of claim 1, wherein the progesterone is released at a steady rate for about 1 day to about 7 days.

11. The method of claim 1, wherein the polysiloxane elastomer is a dimethylpolysiloxane elastomer, and wherein the ratio of progesterone to elastomer is about 1:1 to about 1:10, the progesterone is homogeneously dispersed in the elastomer, the ratio of progesterone to hydrocarbon or glycerol esters of a fatty acid is about 1:0.1 to about 1:100, and wherein the progesterone is released from the monolithic intravaginal ring for up to about 18 days after administration to the patient.

12. The method of claim 1, wherein the intravaginal ring comprises:

(a) about 15% to about 25% by weight of the progesterone;

(b) about 70% to about 80% by weight of a dimethylpolysiloxane elastomer; and

(c) about 1% to about 10% by weight of the pharmaceutically acceptable hydrocarbon or glycerol esters of a fatty acid,

wherein the progesterone is homogeneously dispersed in the elastomer, and wherein the progesterone is released from the monolithic intravaginal ring for up to about 18 days after administration to the patient.

13. A monolithic intravaginal ring for treating a luteal phase defect in a patient in need thereof, the ring comprising:

(a) about 5% to about 40% by weight of progesterone;

(b) about 55% to about 90% by weight of polysiloxane elastomer; and

(c) about 0.1% to about 10% by weight of a pharmaceutically acceptable hydrocarbon or glycerol esters of a fatty acid,

wherein the progesterone is homogeneously dispersed in the elastomer.

14. A process for making a monolithic intravaginal ring, the process comprising:

(a) mixing progesterone, a pharmaceutically acceptable hydrocarbon or glycerol esters of a fatty acid, and a polysiloxane to form a homogeneous mixture;

(b) placing the homogeneous mixture into a mold; and

(c) curing the mold at about 60 °C to about 180 °C,

wherein the polysiloxane is present in a concentration of about 55% to about 90% by total weight of the ring.

15. The process of claim 14, wherein the polysiloxane is vinyl end blocked.

16. The process of claim 14, wherein the polysiloxane is dimethylpolysiloxane.

17. The process of claim 14, further comprising mixing a second polysiloxane into the homogeneous mixture prior to placing into the mold.

18. The process of claim 17, wherein the second polysiloxane is a crosslinker.

19. The process of claim 18, wherein the crosslinker is dimethylmethylhydrogen polysiloxane.

20. The process of claim 14, wherein the placing of the homogeneous mixture is by injection.

21. The method of claim 11, wherein the progesterone is released from the intravaginal ring at about 10 mg/day to about 40 mg/day in vivo.

22. The method of claim 11, wherein the progesterone is released from the intravaginal ring at about 10 mg/day to about 30 mg/day in vivo.

23. The method of claim 11, wherein the progesterone is released from the intravaginal ring at about 15 mg/day to about 25 mg/day in vivo.

24. The method of claim 11, wherein the intravaginal ring is replaced after about 7 days following administration to the patient.

25. The method of claim 23, wherein the intravaginal ring is replaced after about 7 days following administration to the patient.

26. A method for treating a luteal phase defect in a patient in need thereof, the method comprising administering to the patient a monolithic intravaginal ring comprising:

(a) a therapeutically effective amount of progesterone;

(b) a polysiloxane elastomer; and

(c) a pharmaceutically acceptable oil,

wherein the polysiloxane elastomer is present in a concentration of about 55% to about 90% by total weight of the ring.

27. The method of claim 26, wherein the progesterone is homogeneously dispersed in the polysiloxane elastomer.

28. The method of claim 26, wherein the polysiloxane elastomer is a diorganopolysiloxane elastomer.

29. The method of claim 28, wherein the diorganopolysiloxane elastomer is dimethylpolysiloxane elastomer.

30. The method of claim 29, wherein the dimethylpolysiloxane elastomer further comprises a dimethylmethylhydrogen polysiloxane crosslink.

31. The method of claim 26, wherein the pharmaceutically acceptable oil is present in a concentration of about 0.1% to about 10% by total weight of the ring.

32. The method of claim 31, wherein the pharmaceutically acceptable oil is selected from mineral oil, silicone oil and combinations thereof.

33. The method of claim 31, wherein the pharmaceutically acceptable oil is mineral oil.

34. The method of claim 26, wherein the progesterone is present in a concentration of about 15% to about 30% by total weight of the ring.

35. The method of claim 26, wherein the intravaginal ring comprises:

the progesterone, a dimethylpolysiloxane elastomer, and a pharmaceutically acceptable oil, in a ratio of about 4:15:1, respectively, wherein the progesterone is homogeneously dispersed in the elastomer, and wherein the progesterone is released from the monolithic intravaginal ring for up to about 18 days after administration to the patient.

36. The method of claim 26, wherein the intravaginal ring comprises:

(a) about 15% to about 25% by weight of the progesterone;

(b) about 70% to about 80% by weight of a dimethylpolysiloxane elastomer; and

(c) about 1% to about 10% by weight of a pharmaceutically acceptable oil, wherein the progesterone is homogeneously dispersed in the elastomer, and wherein the progesterone is released from the monolithic intravaginal ring for up to about 18 days after administration to the patient.

37. A monolithic intravaginal ring for treating a luteal phase defect in a patient in need thereof, the ring comprising:

(a) about 5% to about 40% by weight of progesterone;

(b) about 55% to about 90% by weight of polysiloxane elastomer; and

(c) about 0.1% to about 10% by weight of a pharmaceutically acceptable oil, wherein the progesterone is homogeneously dispersed in the elastomer.

38. A process for making a monolithic intravaginal ring, the process comprising:

(a) mixing progesterone, a pharmaceutically acceptable oil, and a polysiloxane to form a homogeneous mixture; and

(b) placing the homogeneous mixture into a mold,

wherein the polysiloxane is present in a concentration of about 55% to about 90% by total weight of the ring.

39. The process of claim 38, wherein the progesterone is released from the monolithic intravaginal ring at a steady rate for up to about 10 days after administration to a patient.

40. The process of claim 38, wherein the progesterone is released from the monolithic intravaginal ring for up to about 14 days after administration to a patient.

41. The process of claim 38, wherein the progesterone is released from the monolithic intravaginal ring at a steady rate for up to about 18 days after administration to a patient.

42. The process of claim 38, wherein the polysiloxane is vinyl end blocked.

43. The process of claim 38, wherein the polysiloxane is dimethylpolysiloxane.

44. The process of claim 38, further comprising mixing a second polysiloxane into the homogeneous mixture prior to placing into the mold.

45. The process of claim 44, wherein the second polysiloxane is a crosslinker.

46. The process of claim 45, wherein the crosslinker is dimethylmethylhydrogen polysiloxane.

47. The process of claim 38, wherein the placing of the homogeneous mixture is by injection.

48. The method of claim 36, wherein the progesterone is released from the intravaginal ring at about 10 mg/day to about 40 mg/day in vivo.

49. The method of claim 36, wherein the progesterone is released from the intravaginal ring at about 10 mg/day to about 30 mg/day in vivo.

50. The method of claim 36, wherein the progesterone is released from the intravaginal ring at about 15 mg/day to about 25 mg/day in vivo.

51. The method of claim 36, wherein the intravaginal ring is replaced after about 7 days following administration to the patient.

52. The method of claim 48, wherein the intravaginal ring is replaced after about 7 days following administration to the patient.

Claims

1. Use of

(a) a therapeutically effective amount of progesterone;

(b) a polysiloxane elastomer; and

(c) a pharmaceutically acceptable hydrocarbon or glycerol esters of a fatty acid, in the manufacture of a monolithic intravaginal ring for treating a luteal phase defect in a patient in need thereof,

wherein the polysiloxane elastomer is present in a concentration of 55% to 90% by total weight of the ring.

2. The use of claim 1, wherein the progesterone is homogeneously dispersed in the polysiloxane elastomer.

3. The use of claim 1, wherein the polysiloxane elastomer is a diorganopolysiloxane elastomer.

4. The use of claim 3, wherein the diorganopolysiloxane elastomer is dimethylpolysiloxane elastomer.

5. The use of claim 4, wherein the dimethylpolysiloxane elastomer further comprises a dimethylmethylhydrogen polysiloxane crosslink.

6. The use of claim 1, wherein the pharmaceutically acceptable hydrocarbon or glycerol esters of a fatty acid is present in a concentration of 0.1% to 10% by total weight of the ring.

7. The use of claim 1, wherein the progesterone is present in a concentration of 15% to 30% by total weight of the ring.

8. The use of claim 1, wherein the progesterone is released at a steady rate for 1 day to 14 days.

9. The use of claim 1, wherein the progesterone is released at a steady rate for 1 day to 10 days.

10. The use of claim 1, wherein the progesterone is released at a steady rate for 1 day to 7 days.

11. The use of claim 1, wherein the polysiloxane elastomer is a dimethylpolysiloxane elastomer, and wherein the ratio of progesterone to elastomer is 1:1 to 1:10, the progesterone is homogeneously dispersed in the elastomer, the ratio of progesterone to hydrocarbon or glycerol esters of a fatty acid is 1:0.1 to 1:100, and wherein

the progesterone is released from the monolithic intravaginal ring for up to 18 days after administration to the patient.

12. The use of claim 1, wherein the intravaginal ring comprises:

(a) 15% to 25% by weight of the progesterone;

(b) 70% to 80% by weight of a dimethylpolysiloxane elastomer; and

(c) 1% to 10% by weight of the pharmaceutically acceptable hydrocarbon or glycerol esters of a fatty acid, wherein the progesterone is homogeneously dispersed in the elastomer, and wherein the progesterone is released from the monolithic intravaginal ring for up to 18 days after administration to the patient.

13. A monolithic intravaginal ring for treating a luteal phase defect in a patient in need thereof, the ring comprising:

(a) 5% to 40% by weight of progesterone;

(b) 55% to 90% by weight of polysiloxane elastomer; and

(c) 0.1% to 10% by weight of a pharmaceutically acceptable hydrocarbon or glycerol esters of a fatty acid, wherein the progesterone is homogeneously dispersed in the elastomer.

14. A process for making a monolithic intravaginal ring, the process comprising:

(a) mixing progesterone, a pharmaceutically acceptable hydrocarbon or glycerol esters of a fatty acid, and a polysiloxane to form a homogeneous mixture;

(b) placing the homogeneous mixture into a mold; and

(c) curing the mold at 60 ^{0}C to 180 ^{0}C,

wherein the polysiloxane is present in a concentration of 55% to 90% by total weight of the ring.

15. The process of claim 14, wherein the polysiloxane is vinyl end blocked.

16. The process of claim 14, wherein the polysiloxane is dimethylpolysiloxane.

17. The process of claim 14, further comprising mixing a second polysiloxane into the homogeneous mixture prior to placing into the mold.

18. The process of claim 17, wherein the second polysiloxane is a crosslinker.

19. The process of claim 18, wherein the crosslinker is dimethylmethylhydrogen polysiloxane.

20. The process of claim 14, wherein the placing of the homogeneous mixture is by injection.

21. The use of claim 11, wherein the progesterone is released from the intravaginal ring at 10 mg/day to 40 mg/day in vivo.

22. The use of claim 11, wherein the progesterone is released from the intravaginal ring at 10 mg/day to 30 mg/day in vivo.

23. The use of claim 11, wherein the progesterone is released from the intravaginal ring at 15 mg/day to 25 mg/day in vivo.

24. The use of claim 11, wherein the intravaginal ring is replaced after 7 days following administration to the patient.

25. The use of claim 23, wherein the intravaginal ring is replaced after 7 days following administration to the patient.

26. Use of

(a) a therapeutically effective amount of progesterone;

(b) a polysiloxane elastomer; and

(c) a pharmaceutically acceptable oil

in the manufacture of a monolithic intravaginal ring for treating a luteal phase defect in a patient in need thereof,

wherein the polysiloxane elastomer is present in a concentration of 55% to 90% by total weight of the ring.

27. The use of claim 26, wherein the progesterone is homogeneously dispersed in the polysiloxane elastomer.

28. The use of claim 26, wherein the polysiloxane elastomer is a diorganopolysiloxane elastomer.

29. The use of claim 28, wherein the diorganopolysiloxane elastomer is dimethylpolysiloxane elastomer.

30. The use of claim 29, wherein the dimethylpolysiloxane elastomer further comprises a dimethylmethylhydrogen polysiloxane crosslink.

31. The use of claim 26, wherein the pharmaceutically acceptable oil is present in a concentration of 0.1% to 10% by total weight of the ring.

32. The use of claim 31, wherein the pharmaceutically acceptable oil is selected from mineral oil, silicone oil and combinations thereof.

33. The use of claim 31, wherein the pharmaceutically acceptable oil is mineral oil.

34. The use of claim 26, wherein the progesterone is present in a concentration of 15% to 30% by total weight of the ring.

35. The use of claim 26, wherein the intravaginal ring comprises:

the progesterone, a dimethylpolysiloxane elastomer, and a pharmaceutically acceptable oil, in a ratio of 4:15:1, respectively, wherein the progesterone is homogeneously dispersed in the elastomer, and wherein the progesterone is released from the monolithic intravaginal ring for up to 18 days after administration to the patient.

36. The use of claim 26, wherein the intravaginal ring comprises:

(a) 15% to 25% by weight of the progesterone;

(b) 70% to 80% by weight of a dimethylpolysiloxane elastomer; and

(c) 1% to 10% by weight of a pharmaceutically acceptable oil,

wherein the progesterone is homogeneously dispersed in the elastomer, and wherein the progesterone is released from the monolithic intravaginal ring for up to 18 days after administration to the patient.

37. A monolithic intravaginal ring for treating a luteal phase defect in a patient in need thereof, the ring comprising:

(a) 5% to 40% by weight of progesterone;

(b) 55% to 90% by weight of polysiloxane elastomer; and

(c) 0.1% to 10% by weight of a pharmaceutically acceptable oil,

wherein the progesterone is homogeneously dispersed in the elastomer.

38. A process for making a monolithic intravaginal ring, the process comprising:

(a) mixing progesterone, a pharmaceutically acceptable oil, and a polysiloxane to form a homogeneous mixture; and

(b) placing the homogeneous mixture into a mold, wherein the polysiloxane is present in a concentration of 55% to 90% by total weight of the ring.

39. The process of claim 38, wherein the progesterone is released from the monolithic intravaginal ring at a steady rate for up to 10 days after administration to a patient.

40. The process of claim 38, wherein the progesterone is released from the monolithic intravaginal ring for up to 14 days after administration to a patient.

41. The process of claim 38, wherein the progesterone is released from the monolithic intravaginal ring at a steady rate for up to 18 days after administration to a patient.

42. The process of claim 38, wherein the polysiloxane is vinyl end blocked.

43. The process of claim 38, wherein the polysiloxane is dimethylpolysiloxane.

44. The process of claim 38, further comprising mixing a second polysiloxane into the homogeneous mixture prior to placing into the mold.

45. The process of claim 44, wherein the second polysiloxane is a crosslinker.

46. The process of claim 45, wherein the crosslinker is dimethylmethylhydrogen polysiloxane.

47. The process of claim 38, wherein the placing of the homogeneous mixture is by injection.

48. The use of claim 36, wherein the progesterone is released from the intravaginal ring at 10 mg/day to 40 mg/day in vivo.

49. The use of claim 36, wherein the progesterone is released from the intravaginal ring at 10 mg/day to 30 mg/day in vivo.

50. The use of claim 36, wherein the progesterone is released from the intravaginal ring at 15 mg/day to 25 mg/day in vivo.

51. The use of claim 36, wherein the intravaginal ring is replaced after 7 days following administration to the patient.

52. The use of claim 48, wherein the intravaginal ring is replaced after about 7 days following administration to the patient.