CLAIMS

1. A glucocorticoid contained in a delayed-release dosage form for use in the treatment of a patient suffering from signs and symptoms of an underlying rheumatic disease and/or ostheoarthritis.

2. A glucocorticoid contained in a delayed-release dosage form for use in the treatment of a patient suffering from morning stiffness and pain due to an underlying rheumatic disease and/or osteoarthritis.

3. A glucocorticoid contained in a delayed-release dosage form for use according to claim 1 or 2, wherein said treatment is administered once daily for at least two weeks.

4. A glucocorticoid contained in a delayed-release dosage form for use in the treatment of a patient having daily fluctuations in interleukin 6 levels due to underlying inflammation.

5. A glucocorticoid contained in a delayed-release dosage form for use according to claim 4, wherein said treatment is administered once daily for at least two weeks and wherein the delayed release dosage form is administered such that the glucocorticoid is released at or before the time when the patient's interleukin 6 level is at a daily peak, e.g. between 4 and 8 a.m.

6. A glucocorticoid contained in a delayed-release dosage form for use according to any of claims 1 to 5, wherein said treatment is administered once daily for at least four weeks, for at least eight weeks, for at least twelve weeks or for at least twelve months.

7. A glucocorticoid contained in a delayed-release dosage form for use according to any one of the previous claims, wherein the glucocorticoid dose is exceeding 10 mg/day of prednisone or an equivalent amount of another glucocorticoid at the initiation of the therapy, and/or wherein the glucocorticoid dose is equal or less than 10 mg/day of prednisone or an equivalent amount of another glucocorticoid for maintenance therapy.

8. A glucocorticoid contained in a delayed-release dosage form for use according to any one of the previous claims, wherein the rheumatic disease is rheumatoid arthritis, ankylosating spondylitis and/or polymyalgia rheumatica.

9. A glucocorticoid contained in a delayed-release dosage form for use according to any one of the previous claims, wherein said patient has or has not been treated previously with a oral immediate release glucocorticoid, and/or a NSAID, a DMARD, a TNFαinhibitor, an IL-1 inhibitor, an IL-6 inhibitor, an analgetic agent, or combinations thereof.

10. A glucocorticoid contained in a delayed-release dosage form for use according to claim 9, wherein said patient is refractory to said treatment with an oral immediate release dosage form of a glucocorticoid or wherein an immediate release dosage form of a glucocorticoid is replaced by the said delayed release dosage form.

11. A glucocorticoid contained in a delayed-release dosage form for use according to any one of the previous claims, wherein the treatment further comprises administering to said patient an effective amount of a NSAID, a DMARD, a TNFα inhibitor, an IL-1 inhibitor, an IL-6 inhibitor, an analgetic agent, or combinations thereof.

12. A glucocorticoid contained in a delayed-release dosage form for use according to any one of the previous claims, wherein said treatment consists of administering to said patient an effective amount of a glucocorticoid contained in a delayed-release dosage form, wherein said treatment is administered once daily for at least two weeks.

13. A glucocorticoid contained in a delayed-release dosage form for use according to any one of the previous claims, wherein the delayed-release dosage form has a lag time of from 2 hours to 6 hours, preferably of from 3 hours to 5 hours after administration and/or a dissolution time of equal or less than 2 hours after the lag time is reached.

14. A gucocorticoid contained in a delayed-release dosage form for use according to any one of the previous claims, wherein the delayed-release dosage form has a drug release behaviour which is independent from pH.

15. A glucocorticoid contained in a delayed-release dosage form for use according to any one of the previous claims, wherein the delayed release dosage form is a tablet or a capsule and/or comprises a non-soluble/ non-swellable coating and a core comprising the active agent and a disintegrant and/or a swelling agent.

16. A glucocorticoid contained in a delayed-release dosage form for use according to any one of the previous claims, wherein the glucocorticoid is cortisone, hydrocortisone, prednisone, prednisolone, methylprednisolone, budesonide, dexamethasone, fludrocortisone, fluocortolone, cloprednole, deflazacort, triamcinolone, preferably prednisone or prednisolone, and the corresponding salts and esters thereof.

17. A glucocorticoid contained in a delayed-release dosage form for use according to any one of the previous claims, wherein said delayed-release dosage form is effective at a lower dose of glucocorticoid as compared to the administration of said glucocorticoid in an immediate release dosage form.

18. A glucocorticoid contained in a delayed-release dosage form for use according to any one of the previous claims, wherein said patient suffers from inflammation.

19. A glucocorticoid contained in a delayed-release dosage form for use according to any one of the previous claims, wherein the glucocorticoid is administered in the evening, preferably between 9:00 pm and 11:00 pm.

20. A glucorticoid contained in a delayed-release dosage form for use according to claim 4 or 5, wherein the increased Interleukin 6 levels are caused by a rheumatic disease, e.g. wherein the rheumatic disease is selected from the group consisting of rheumatoid arthritis, ankylosating spondylitis, polymyalgia rheumatica, and combinations thereof.

21. Use of a glucocorticoid contained in a delayed-release dosage form in the manufacture of a medicament for treatment of a patient suffering from signs and symptoms of an underlying rheumatic disease and/or ostheoarthritis.

22. Use of a glucocorticoid contained in a delayed-release dosage form in the manufacture of a medicament for treatment of a patient suffering from morning stiffness and pain due to an underlying rheumatic disease and/or osteoarthritis.

23. Use according to claim 21 or 22, wherein said medicament is to be administered once daily for at least two weeks.

24. Use of a glucocorticoid contained in a delayed-release dosage form in the manufacture of a medicament for treatment of a patient having daily fluctuations in Interleukin 6 levels due to underlying inflammation.

25. Use according to claim 24, wherein said medicament is to be administered once daily for at least two weeks and wherein the delayed release dosage form is administered such that the glucocorticoid is released at or before the time when the patient's Interleukin 6 level is at a daily peak, e.g. between 4 and 8 a.m.

26. Use according to any one of claims 21-25, wherein said medicament is to be administered once daily for at least four weeks, for at least eight weeks, for at least twelve weeks or for at least twelve months.

27. Use according to any one of claims 21-26, wherein the glucocorticoid dose is exceeding 10 mg/day of prednisone or an equivalent amount of another glucocorticoid at the initiation of the therapy, and/or wherein the glucocorticoid dose is equal or less than 10 mg/day of prednisone or an equivalent amount of another glucocorticoid for maintenance therapy.

28. Use according to any one of claims 21-27, wherein the rheumatic disease is rheumatoid arthritis, ankylosating spondylitis and/or polymyalgia rheumatica.

29. Use according to any one of claims 21-28, wherein said patient has or has not been treated previously with a oral immediate release glucocorticoid, and/or a NSAID, a DMARD, a TNFα inhibitor, an IL-1 inhibitor, an IL-6 inhibitor, an analgetic agent, or combinations thereof.

30. Use according to claim 29, wherein said patient is refractory to said medicament with an oral immediate release dosage form of a glucocorticoid or wherein an immediate release dosage form of a glucocorticoid is replaced by the said delayed release dosage form.

31. Use according to any one of claims 21-30, wherein the medicament further comprises an effective amount of a NSAID, a DMARD, a TNFα inhibitor, an IL-1 inhibitor, an IL-6 inhibitor, an analgetic agent, or combinations thereof.

32. Use according to any one of claims 21-31, wherein said medicament further comprises of an effective amount of a glucocorticoid contained in a delayed-release dosage form, and wherein said medicament is to be administered once daily for at least two weeks.

33. Use according to any one of claims 21-32, wherein the delayed-release dosage form has a lag time of from 2 hours to 6 hours, preferably of from 3 hours to 5 hours after administration and/or a dissolution time of equal or less than 2 hours after the lag time is reached.

34. Use according to any one of claims 21-33, wherein the delayed-release dosage form has a drug release behaviour which is independent from pH.

35. Use according to any one of claims 21-34, wherein the delayed release dosage form is a tablet or a capsule and/or comprises a non-soluble/ non-swellable coating and a core comprising the active agent and a disintegrant and/or a swelling agent.

36. Use according to any one of claims 21-35, wherein the glucocorticoid is cortisone, hydrocortisone, prednisone, prednisolone, methylprednisolone, budesonide, dexamethasone, fludrocortisone, fluocortolone, cloprednole, deflazacort, triamcinolone, preferably prednisone or prednisolone, and the corresponding salts and esters thereof.

37. Use according to any one of claims 21-36, wherein said delayed-release dosage form is effective at a lower dose of glucocorticoid as compared to the administration of said glucocorticoid in an immediate release dosage form.

38. Use according to any one of claims 21-37, wherein said patient suffers from inflammation.

39. Use according to any one of claims 21-38, wherein the glucocorticoid is to be administered in the evening, preferably between 9:00 pm and 11:00 pm.

40. Use according to claim 24 or 25, wherein the increased Interleukin 6 levels are caused by a rheumatic disease, e.g. wherein the rheumatic disease is selected from the group consisting of rheumatoid arthritis, ankylosating spondylitis, polymyalgia rheumatica, and combinations thereof.

CLAIMS

1. A glucocorticoid contained in a delayed-release dosage form for use in the treatment of a patient suffering from signs and symptoms of an underlying rheumatic disease and/or ostheoarthritis, wherein said treatment is to be administered once daily for at least two weeks and wherein the delayed-release dosage form has a drug release behaviour which is independent from pH.

2. A glucocorticoid contained in a delayed-release dosage form for use in the treatment of a patient suffering from morning stiffness and pain due to an underlying rheumatic disease and/or osteoarthritis, wherein said treatment is to be administered once daily for at least two weeks and wherein the delayed-release dosage form has a drug release behaviour which is independent from pH.

3. A glucocorticoid contained in a delayed-release dosage form for use in the treatment of a patient having daily fluctuations in Interleukin 6 levels due to underlying inflammation, wherein said treatment is to be administered once daily for at least two weeks and wherein the delayed-release dosage form has a drug release behaviour which is independent from pH.

4. A glucocorticoid contained in a delayed-release dosage form for use according to claim 3, wherein the delayed release dosage form is to be administered such that the glucocorticoid is released at or before the time when the patient's Interleukin 6 level is at a daily peak, e.g. between 4 and 8 a.m.

5. A glucocorticoid contained in a delayed-release dosage form for use according to any of claims 1 to 4, wherein said treatment is to be administered once daily for at least four weeks, for at least eight weeks, for at least twelve weeks or for at least twelve months.

6. A glucocorticoid contained in a delayed-release dosage form for use according to any one of the previous claims, wherein the rheumatic disease is rheumatoid arthritis, ankylosating spondylitis and/or polymyalgia rheumatica.

7. A glucocorticoid contained in a delayed-release dosage form for use according to any one of the previous claims, wherein said patient has or has not been treated previously with a oral immediate release glucocorticoid, and/or a NSAID, a DMARD, a TNFα inhibitor, an IL-1 inhibitor, an IL-6 inhibitor, an analgetic agent, or combinations thereof.

8. A glucocorticoid contained in a delayed-release dosage form for use according to any one of the previous claims, wherein said treatment is to be administered with an effective amount of a NSAID, a DMARD, a TNFα inhibitor, an IL-1 inhibitor, an IL-6 inhibitor, an analgetic agent, or combinations thereof.

9. A glucocorticoid contained in a delayed-release dosage form for use according to any one of the previous claims, wherein the delayed-release dosage form has a lag time of from 2 hours to 6 hours, preferably of from 3 hours to 5 hours after administration and/or a dissolution time of equal or less than 2 hours after the lag time is reached.

10. A glucocorticoid contained in a delayed-release dosage form for use according to any one of the previous claims, wherein the delayed release dosage form is a tablet or a capsule and/or comprises a non-soluble/ non-swellable coating and a core comprising the active agent and a disintegrant and/or a swelling agent.

11. A glucocorticoid contained in a delayed-release dosage form for use according to any one of the previous claims, wherein the glucocorticoid is cortisone, hydrocortisone, prednisone, prednisolone, methylprednisolone, budesonide, dexamethasone, fludrocortisone, fluocortolone, cloprednole, deflazacort, triamcinolone, preferably prednisone or prednisolone, and the corresponding salts and esters thereof.

12. A glucocorticoid contained in a delayed-release dosage form for use according to any one of the previous claims, wherein said patient suffers from inflammation.

13. A glucocorticoid contained in a delayed-release dosage form for use according to any one of the previous claims, wherein the glucocorticoid is to be administered in the evening, preferably between 9:00 pm and 11:00 pm.

14. A glucorticoid contained in a delayed-release dosage form for use according to claim 4 or 5, wherein the increased Interleukin 6 levels are caused by a rheumatic disease, e.g. wherein the rheumatic disease is selected from the group consisting of rheumatoid arthritis, ankylosating spondylitis, polymyalgia rheumatica, and combinations thereof.

15. Use of a glucocorticoid contained in a delayed-release dosage form in the manufacture of a medicament for treatment of a patient suffering from signs and symptoms of an underlying rheumatic disease and/or ostheoarthritis wherein said treatment is to be administered once daily for at least two weeks and wherein the delayed-release dosage form has a drug release behaviour which is independent from pH.

16. Use of a glucocorticoid contained in a delayed-release dosage form in the manufacture of a medicament for treatment of a patient suffering from morning stiffness and pain due to an underlying rheumatic disease and/or osteoarthritis wherein said treatment is to be administered once daily for at least two weeks and wherein the delayed-release dosage form has a drug release behaviour which is independent from pH.

17. Use of a glucocorticoid contained in a delayed-release dosage form in the manufacture of a medicament for treatment of a patient having daily fluctuations in Interleukin 6 levels due to underlying inflammation wherein said treatment is to be administered once daily for at least two weeks and wherein the delayed-release dosage form has a drug release behaviour which is independent from pH.

18. Use according to claim 17, wherein the delayed release dosage form is to be administered such that the glucocorticoid is released at or before the time when the patient's Interleukin 6 level is at a daily peak, e.g. between 4 and 8 a.m.

19. Use according to any one of claims 15-18, wherein said medicament is to be administered

once daily for at least four weeks, for at least eight weeks, for at least twelve weeks or for at least twelve months.

20. Use according to any one of claims 15-19, wherein the rheumatic disease is rheumatoid arthritis, ankylosating spondylitis and/or polymyalgia rheumatica.

21. Use according to any one of claims 15-20, wherein said patient has or has not been treated previously with a oral immediate release glucocorticoid, and/or a NSAID, a DMARD, a TNFα inhibitor, an IL-1 inhibitor, an IL-6 inhibitor, an analgetic agent, or combinations thereof.

22. Use according to any one of claims 15-21, wherein the medicament further comprises an effective amount of a NSAID, a DMARD, a TNFα inhibitor, an IL-1 inhibitor, an IL-6 inhibitor, an analgetic agent, or combinations thereof.

23. Use according to any one of claims 15-22, wherein the delayed-release dosage form has a lag time of from 2 hours to 6 hours, preferably of from 3 hours to 5 hours after administration and/or a dissolution time of equal or less than 2 hours after the lag time is reached.

24. Use according to any one of claims 15-23, wherein the delayed release dosage form is a tablet or a capsule and/or comprises a non-soluble/ non-swellable coating and a core comprising the active agent and a disintegrant and/or a swelling agent.

25. Use according to any one of claims 15-24, wherein the glucocorticoid is cortisone, hydrocortisone, prednisone, prednisolone, methylprednisolone, budesonide, dexamethasone, fludrocortisone, fluocortolone, cloprednole, deflazacort, triamcinolone, preferably prednisone or prednisolone, and the corresponding salts and esters thereof.

26. Use according to any one of claims 15-25, wherein said patient suffers from inflammation.

27. Use according to any one of claims 15-26, wherein the glucocorticoid is to be administered in the evening, preferably between 9:00 pm and 11:00 pm.

28. Use according to claim 17 or 18, wherein the increased Interleukin 6 levels are caused by a rheumatic disease, e.g. wherein the rheumatic disease is selected from the group consisting of rheumatoid arthritis, ankylosating spondylitis, polymyalgia rheumatica, and combinations thereof.