CLAIMS

1. The use of an interferon-β-1a in the manufacture of a medicament for reducing the severity of flu-like symptoms associated with treating a patient having multiple sclerosis with intramuscularly administered interferon-β-1a over an eight week period,

wherein the medicament is to be administered intramuscularly once a week to a patient having multiple sclerosis according to a first schedule comprising:

intramuscular administration of 7.5 μg of interferon-β-1a to the patient in week one;

intramuscular administration of 15 μg of interferon-β-1a to the patient in week two;

intramuscular administration of 22.5 μg of interferon-β-1a to the patient in week three; and

intramuscular administration of 30 μg of interferon-β-1a to the patient in week four and each week thereafter,

wherein the severity of the flu-like symptoms is reduced at 4-6 hours and at 12-15 hours after each intramuscular administration of interferon-β-1a throughout the eight week period

(i) when compared to the severity of the flu-like symptoms at 4-6 hours and at 12-15 hours after each intramuscular administration of the medicament in a second schedule comprising once a week intramuscular administration of 30 μg of interferon-β-1a to a patient having multiple sclerosis for eight weeks; and

(ii) when compared to the severity of the flu-like symptoms at 4-6 hours and at 12-15 hours after each intramuscular administration of the medicament in a once a week intramuscular administration of the medicament to a patient having multiple sclerosis according to a third schedule comprising:

intramuscular administration of 7.5 μg of interferon-β-1a to the patient in weeks one and two;

intramuscular administration of 15 μg of interferon-β-1a to the patient in weeks three and four;

intramuscular administration of 22.5 μg of interferon-β-1a to the patient in weeks five and six; and

intramuscular administration of 30 μg of interferon-β-1a to the patient in week seven and each week thereafter.

2. The use of claim 1, wherein the flu-like symptoms include fever, muscle aches, chills, sweating, fatigue, headache, and malaise.

3. The use of claim 1 or 2, further comprising administration of an analgesic or anti-inflammatory drug, or a mixture thereof.

4. The use of claim 3, wherein the drug is a steroid.

5. The use of claim 3, wherein the drug is a non-steroidal anti-inflammatory agent.

6. The use of claim 3, wherein the drug is acetaminophen.

7. The use of claim 3, wherein the drug is ibuprofen.

8. A titration package for reducing the severity of flu-like symptoms associated with treating a patient having multiple sclerosis with intramuscularly administered interferon-β-1a over an eight week period,

wherein the titration package comprises interferon-β-1a and delivery devices for once a week intramuscular administration to a patient having multiple sclerosis according to a first schedule comprising:

a first delivery device for intramuscular administration of 7.5 μg of interferon-β-1a to the patient in week one;

a second delivery device for intramuscular administration of 15 μg of interferon-β-1a to the patient in week two; and

a third delivery device for intramuscular administration of 22.5 μg of interferon-β-1a to the patient in week three;

wherein the severity of the flu-like symptoms is reduced at 4-6 hours and at 12-15 hours after each intramuscular administration of interferon-β-1a throughout an eight week period which includes once a week intramuscular administration of 30 μg of interferon-β-1a to the patient in week four through eight,

(i) when compared to the severity of the flu-like symptoms at 4-6 hours and at 12-15 hours after each intramuscular administration of interferon-β-1a in a second schedule comprising once a week intramuscular administration of 30 μg of interferon-β-1a to a patient having multiple sclerosis for eight weeks; and

(ii) when compared to the severity of the flu-like symptoms at 4-6 hours and at 12-15 hours after each intramuscular administration of interferon-β-1a in a once a week intramuscular administration of the medicament to a patient having multiple sclerosis according to a third schedule comprising:

intramuscular administration of 7.5 μg of interferon-β-1a to the patient in weeks one and two;

intramuscular administration of 15 μg of interferon-β-1a to the patient in weeks three and four;

intramuscular administration of 22.5 μg of interferon-β-1a to the patient in weeks five and six; and

intramuscular administration of 30 μg of interferon-β-1a to the patient in week seven and eight.

9. The titration package of claim 8, further comprising vials containing the interferon-β-1a in lyophilized form.

10. The titration package of claim 9, further comprising a vial adapter and the delivery devices are syringes pre-filled with a diluent for said lyophilized interferon-β-1a.

11. The titration package of claim 8, wherein the delivery devices are pre-filled syringes containing correct dosages of interferon-β-1a in liquid form.

12. The titration package of claim 8, wherein the delivery device comprises an auto-injector.

13. The titration package of claim 8, wherein the delivery device is needle-free.

14. The titration package of claim 8, wherein the delivery device is a pen.

15. The titration package of claim 8, further comprising a needle stick prevention device.

16. The titration package of claim 15, wherein the needle-stick prevention device comprises a needle shield.

17. The titration package of claim 16, wherein the shield is activated manually by the patient.

18. The titration package of claim 16, wherein the shield is automated.

19. The titration package of claim 18, wherein the automated shield is activated by the patient.

20. The titration package of claim 18, wherein the needle is automatically shielded without any action by the patient.

21. The titration package of claim 18, wherein the needle is shielded without any action by the patient.

22. The titration package of claim 8, wherein the package further comprises a dose-limiting titration device.

23. The titration package of any one of claims 8-22, further comprising an analgesic or anti-inflammatory drug, or a mixture thereof.

24. The titration package of claim 23, wherein the drug is a steroid.

25. The titration package of claim 23, wherein the drug is a non-steroidal anti-inflammatory agent.

26. The titration package of claim 23, wherein the drug is acetaminophen.

27. The titration package of claim 23, wherein the drug is ibuprofen.

CLAIMS:

1. The use of an interferon in the manufacturer of a medicament for treating multiple sclerosis, wherein the medicament is to be administered intramuscularly to a patient once per week, wherein treatment begins with a titration period, wherein the interferon is to be administered at a one-quarter dose in week one, a one-half dose in week two, a three-quarter dose in week 3, and a full therapeutically effective dose in week 4 and thereafter.

2. The use of Claim 1, wherein the week one dose is about 7.5 micrograms, the week two dose is about 15 micrograms, the week three dose is about 22.5 micrograms, and the week four dose is about 30 micrograms.

3. The use of claim 1, wherein the interferon is interferon β_{1a}.

4. The use of an interferon in the manufacture of a medicament for reducing flu-like symptoms associated with an interferon that has been administered to a patient with multiple sclerosis, wherein the medicament is to be administered to the patient:

   (a) intramuscularly according to an escalating dosing regimen in weeks 1 to 3; and

   (b) intramuscularly with a full therapeutically effective dose of interferon in week 4.

5. The use of claim 4, wherein the escalating dosing regimen comprises one quarter of the therapeutically effective dose being administered in week 1, half of the therapeutically effective dose in week 2, and three-quarters of the therapeutically effective dose in week 3.

6. The use of claim 4, wherein the interferon is interferon β_{1a}.

7. The use of claim 4, wherein the full therapeutically effective dose is 30 micrograms.

8. The use of claim 4, wherein the flu-like symptoms include fever, muscle aches, chills, sweating, fatigue, headache, and malaise.

9. A titration package for enabling compliance with a regimen of changing dosage of an interferon over a period of time, the package comprising interferon, delivery devices for said interferon, and instructions for intramuscular administration of said interferon by a patient during a titration period, wherein the interferon is administered at a one-quarter dose in week one, a one-half dose in week two, a three-quarter dose in week 3, and a full therapeutically effective dose in week 4.

10. The titration package of Claim 9, wherein the instructions indicate a week one dosage of about 7.5 micrograms, a week two dose of about 15 micrograms, a

week three dosage of about 22.5 micrograms, and a week four dosage of about 30 micrograms.

11. The titration package of Claim 9, wherein the interferon is provided in a vial in lyophilized form.

12. The titration package of Claim 11, further comprising a vial adapter and a syringe pre-filled with a diluent for said lyophilized interferon.

13. The titration package of Claim 9, wherein the interferon is provided in a liquid formulation.

14. The titration package of Claim 13, wherein the liquid interferon formulation is provided in pre-filled syringes.

15. The titration package of Claim 14, wherein the pre-filled syringes are filled with a correct dosage for weeks one to four.

16. The titration package of Claim 9, wherein the delivery device comprises an auto-injector.

17. The titration package of Claim 9, wherein the delivery device is needle-free.

18. The titration package of Claim 9, wherein the delivery device is a pen.

19. The titration package of Claim 9, further comprising a needle stick prevention device.

20. The titration package of Claim 19, wherein the needle-stick prevention device comprises a needle shield.

21. The titration package of Claim 20, wherein the shield is activated manually by the patient.

22. The titration package of Claim 20, wherein the shield is automated.

23. The titration package of Claim 22, wherein the automated shield is activated by the patient.

24. The titration package of Claim 22, wherein the needle is automatically shielded without any action by the patient.

25. The titration package of Claim 22, wherein the needle is shielded without any action by the patient.

26. The titration package of Claim 9, wherein the package further comprises a dose-limiting titration device.

27. The use of any of Claims 1-8, further comprising administration of an analgesic or anti-inflammatory drug, or a mixture thereof.

28. The use of Claim 27, wherein the drug is a steroid.

29. The use of Claim 27, wherein the drug is a non-steroidal anti-inflammatory agent.

30. The use of Claim 27, wherein the drug is acetaminophen.

31. The use of Claim 27, wherein the drug is ibuprofen.