CLAIMS

1. A subcutaneous dosage form of a pharmaceutical composition of a blood coagulation factor selected from the group consisting of Factor VII, Factor VIIa, Factor VIII, Factor IX, Factor X, Factor Xa, Factor XI, Factor XIII, Factor V, von Willebrand's Factor and Protein C conjugated to a polyethylene glycol (PEG) molecule for use in the treatment of a blood clotting disease or trauma in a patient, in which the dosage form is administered to the patient at intervals whereby normal haemostasis is maintained and in which the PEG molecule is conjugated directly or indirectly to the blood coagulation factor via a serine or threonine residue, via a hydroxyl residue on a sugar residue, via a single cysteine residue, or via an amide, N-terminal amino group, or a carboxyl group.

2. A dosage form according to Claim 1, in which the blood coagulation factor is Factor VIII.

3. A dosage form according to Claim 1, in which the blood coagulation factor is Factor IX.

4. A dosage form according to Claim 1, in which the blood coagulation factor is Factor VIIa.

5. A dosage form according to any preceding claim, in which the dosage form comprises an excipient.

6. A dosage form according to Claim 5, in which the excipient is selected from the group consisting of liposomes, saline, buffered saline, dextrose, water, glycerol, ethanol, and combinations thereof.

7. A dosage form according to any preceding claim, in which the dosage of the blood coagulation factor is of from 1 to 1000 IU/kg.

8. A dosage form according to any of Claims 1 to 6, in which the dosage of the blood coagulation factor is of from 5 to 500 IU/kg.

9. A dosage form according to any of Claims 1 to 6, in which the dosage of the blood coagulation factor is of from 100 to 250 IU/kg.

10. A dosage form according to any of Claims 1 to 6, in which the dosage of the blood coagulation factor is of from 50 to 200 IU/kg.

11. A dosage form according to any of Claims 1 to 6, in which the dosage is from 25 to 50 IU/kg.

12. A dosage form according to any of Claims 1 to 6, in which the dosage is from 5 to 50 IU/kg.

13. A dosage form according to any of Claims 1 to 6, in which the dosage form is for administration at least once per day.

14. A dosage form according to Claim 13, in which the dosage form is administered twice per day, in which the patient receives a first dosage form in a first administration and a second dosage form in a second administration.

15. A dosage form according to Claim 14, in which the second dosage form is administered separately, simultaneously or sequentially to the first dosage form.

16. A dosage form of a blood coagulation factor according to any preceding claim for use in the treatment of a blood clotting disease or trauma.

17. A subcutaneous dosage form of a pharmaceutical composition of a blood coagulation factor selected from the group consisting of Factor VII, Factor VIIa, Factor VIII, Factor IX, Factor X, Factor Xa, Factor XI, Factor XIII, Factor V, von Willebrand's Factor and Protein C conjugated to a polyethylene glycol (PEG) molecule, in which the dosage of the blood coagulation factor is from 1 to 1000 IU/kg, and in which the PEG molecule is conjugated directly or indirectly to the blood coagulation factor via a serine or threonine residue, via a hydroxyl residue on a sugar residue, via a single cysteine residue, or via an amide, N-terminal amino group, or a carboxyl group.

18. A subcutaneous dosage form comprising a PEGylated form of a therapeutic agent selected from the group consisting of Factor VII, Factor VIIa, Factor VIII, Factor IX, Factor X, Factor Xa, Factor XI, Factor XIII, Factor V, von Willebrand's Factor and Protein C, in which the PEG is directly or indirectly conjugated to the therapeutic agent; in which repeated subcutaneous administration of the dosage form to a subject before the concentration of the therapeutic agent in the blood reduces to sub-therapeutic levels provides a sustained therapeutic effect in the subject, in which the PEG molecule is conjugated directly or indirectly to the blood coagulation factor via a serine or threonine residue, via a hydroxyl

residue on a sugar residue, via a single cysteine residue, or via an amide, N-terminal amino group, or a carboxyl group.

19. A kit of parts comprising a dosage form according to any preceding claim, and an administration vehicle.

20. Use of a blood coagulation factor selected from the group consisting of Factor VII, Factor VIIa, Factor VIII, Factor IX, Factor X, Factor Xa, Factor XI, Factor XIII, Factor V, von Willebrand's Factor and Protein C conjugated to a polyethylene glycol (PEG) molecule in the preparation of a medicament for the treatment of a blood clotting disease or trauma in a patient, in which the medicament is in a subcutaneous dosage form, in which the dosage form is administered to the patient at intervals whereby normal haemostasis is maintained and in which the PEG molecule is conjugated directly or indirectly to the blood coagulation factor via a serine or threonine residue, via a hydroxyl residue on a sugar residue, via a single cysteine residue, or via an amide, N-terminal amino group, or a carboxyl group.

21. Use of a blood coagulation factor selected from the group consisting of Factor VII, Factor VIIa, Factor VIII, Factor IX, Factor X, Factor Xa, Factor XI, Factor XIII, Factor V, von Willebrand's Factor and Protein C conjugated to a polyethylene glycol (PEG) molecule in the preparation of a subcutaneous dosage form of a pharmaceutical composition, in which the dosage of the blood coagulation factor is from 1 to 1000 IU/kg, and in which the PEG molecule is conjugated directly or indirectly to the blood coagulation factor via a serine or threonine residue, via a hydroxyl residue on a sugar residue, via a single cysteine residue, or via an amide, N-terminal amino group, or a carboxyl group.

22. Use of a PEGylated form of a therapeutic agent selected from the group consisting of Factor VII, Factor VIIa, Factor VIII, Factor IX, Factor X, Factor Xa, Factor XI, Factor XIII, Factor V, von Willebrand's Factor and Protein C, in which the PEG is directly or indirectly conjugated to the therapeutic agent, in the preparation of a subcutaneous dosage form, in which repeated subcutaneous administration of the dosage form to a subject before the concentration of the therapeutic agent in the blood reduces to sub-therapeutic levels provides a sustained therapeutic effect in the subject, in which the PEG molecule is conjugated directly or indirectly to the blood coagulation factor via a serine or threonine residue, via a hydroxyl residue on a sugar residue, via a single cysteine residue, or via an amide, N-terminal amino group, or a carboxyl group.

CLAIMS

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2. Use according to Claim 1, in which the blood coagulation factor is Factor VIII.

3. Use according to Claim 1, in which the blood coagulation factor is Factor IX.

4. Use according to Claim 1, in which the blood coagulation factor is Factor VIIa.

5. Use according to any preceding claim, in which the dosage form comprises an excipient.

6. Use according to Claim 5, in which the excipient is selected from the group consisting of liposomes, saline, buffered saline, dextrose, water, glycerol, ethanol, and combinations thereof.

7. Use according to any preceding claim, in which the dosage of the blood coagulation factor is of from 1 to 1000 IU/kg.

8. Use according to any of Claims 1 to 6, in which the dosage of the blood coagulation factor is of from 5 to 500 IU/kg.

9. Use according to any of Claims 1 to 6, in which the dosage of the blood coagulation factor is of from 100 to 250 IU/kg.

10. Use according to any of Claims 1 to 6, in which the dosage of the blood coagulation factor is of from 50 to 200 IU/kg.

11. Use according to any of Claims 1 to 6, in which the dosage is from 25 to 50 IU/kg.

12. Use according to any of Claims 1 to 6, in which the dosage is from 5 to 50 IU/kg.

13. Use according to any of Claims 1 to 6, in which the dosage form is for administration at least once per day.

14. Use according to Claim 13, in which the dosage form is administered twice per day, in which the patient receives a first dosage form in a first administration and a second dosage form in a second administration.

15. Use according to Claim 14, in which the second dosage form is administered separately, simultaneously or sequentially to the first dosage form.

16. Use according to any preceding claim, in which the pharmaceutical composition is for use in the treatment of a blood clotting disease or trauma.

17. Use of a blood coagulation factor selected from the group consisting of Factor VII, Factor VIIa, Factor VIII, Factor IX, Factor X, Factor Xa, Factor XI, Factor XIII, Factor V, von Willebrand's Factor and Protein C conjugated to a polyethylene glycol (PEG) molecule in the preparation of a subcutaneous dosage form of a pharmaceutical composition, in which the dosage of the blood coagulation factor is from 1 to 1000 IU/kg, and in which the PEG molecule is conjugated directly or indirectly to the blood coagulation factor via a serine or threonine residue, via a hydroxyl residue on a sugar residue, via a single cysteine residue, or via an amide, N-terminal amino group, or a carboxyl group.

18. Use ofa PEGylated form of a therapeutic agent selected from the group consisting of Factor VII, Factor VIIa, Factor VIII, Factor IX, Factor X, Factor Xa, Factor XI, Factor XIII, Factor V, von Willebrand's Factor and Protein C, in which the PEG is directly or indirectly conjugated to the therapeutic agent in the preparation of subcutaneous dosage form of a pharmaceutical composition, in which repeated subcutaneous administration of the dosage form to a subject before the concentration of the therapeutic agent in the blood reduces to sub-therapeutic levels provides a sustained therapeutic effect in the subject, in which the PEG molecule is conjugated directly or indirectly to the blood coagulation factor via a serine or threonine residue, via a hydroxyl residue on a sugar residue, via a single cysteine residue, or via an amide, N-terminal amino group, or a carboxyl group.

19. A kit of parts comprising a dosage form according to any preceding claim, and an administration vehicle.

20. Use of a blood coagulation factor selected from the group consisting of Factor VII, Factor VIIa, Factor VIII, Factor IX, Factor X, Factor Xa, Factor XI, Factor XIII, Factor V, von Willebrand's Factor and Protein C conjugated to a polyethylene glycol (PEG) molecule in the preparation of a medicament for the treatment of a blood clotting disease or trauma in a patient, in which the medicament is in a subcutaneous dosage form, in which the dosage form is administered to the patient at intervals whereby normal haemostasis is maintained and in which the PEG molecule is conjugated directly or indirectly to the blood coagulation factor via a serine or threonine residue, via a hydroxyl residue on a sugar residue, via a single cysteine residue, or via an amide, N-terminal amino group, or a carboxyl group.

21. Use of a blood coagulation factor selected from the group consisting of Factor VII, Factor VIIa, Factor VIII, Factor IX, Factor X, Factor Xa, Factor XI, Factor XIII, Factor V, von Willebrand's Factor and Protein C conjugated to a polyethylene glycol (PEG) molecule in the preparation of a subcutaneous dosage form of a pharmaceutical composition, in which the dosage of the blood coagulation factor is from 1 to 1000 IU/kg, and in which the PEG molecule is conjugated directly or indirectly to the blood coagulation factor via a serine or threonine residue, via a hydroxyl residue on a sugar residue, via a single cysteine residue, or via an amide, N-terminal amino group, or a carboxyl group.

22. Use of a PEGylated form of a therapeutic agent selected from the group consisting of Factor VII, Factor VIIa, Factor VIII, Factor IX, Factor X, Factor Xa, Factor XI, Factor XIII, Factor V, von Willebrand's Factor and Protein C, in which the PEG is directly or indirectly conjugated to the therapeutic agent, in the preparation of a subcutaneous dosage form, in which repeated subcutaneous administration of the dosage form to a subject before the concentration of the therapeutic agent in the blood reduces to sub-therapeutic levels provides a sustained therapeutic effect in the subject, in which the PEG molecule is conjugated directly or indirectly to the blood coagulation factor via a serine or threonine residue, via a hydroxyl residue on a sugar residue, via a single cysteine residue, or via an amide, N-terminal amino group, or a carboxyl group.