CLAIMS

1. Use of a blood coagulation factor replacement product in the manufacture of a medicament for the treatment and prophylaxis of bleedings of a patient having an acquired coagulation factor deficiency or a congenital deficiency of a coagulation factor,

wherein the medicament comprises a product comprising at least isolated prothrombin (Factor II) and isolated Antithrombin III (ATIII),

wherein the molar ratio between ATIII to Factor II is at least 1:30 and the molar ratio between ATIII to Factor II is not higher than 1:0.5; and

wherein administration of the medicament reduces the patient's risk of a thromboembolic complication.

2. The use of claim 1, wherein administration of the product reduces the patient's risk for a thromboembolic complication compared to a reference treatment, wherein the reference treatment is identical to the treatment, except that the molar ratio between ATIII to Factor II of the product used in the reference treatment is below 1:30.

3. The use according to claim 1 or 2, wherein the product further comprises at least one isolated coagulation factor selected from the group consisting of Factor IX, Factor X and Factor VII.

4. The use according to any one of claims 1-3, wherein the amount of blood loss of the patient following treatment with the product is:

i) decreased compared to an amount of blood loss following a placebo treatment or without treatment, and/or

ii) reduced to an amount below 75%, below 70%, below 60%, below 55%, below 50%, below 45%, below 40% or below 35% of the amount following placebo treatment or of the amount without treatment.

5. The use according to any one of claims 1-4, wherein the amount of blood loss of the patient following the treatment with the product is:

i) either essentially identical or only moderately increased when compared to a reference treatment, or

ii) decreased when compared to a reference treatment, or

iii) decreased when compared to a reference treatment by at least 5%, at least 10%, at least 15% or at least 20%, wherein the reference treatment is identical to the

treatment, except that the molar ratio between ATIII to Factor II of the product used in said reference treatment is below 1:30.

6. The use according to any one of claims 1-5, wherein in case of the amount of blood loss of the patient following the treatment with the product is only moderately increased when compared to an amount of blood loss of a reference treatment, the moderate increase amounting to not more than 60%, not more than 50%, not more than 40%, not more than 30%, not more than 20%, not more than 15%, not more than 10% or not more than 5%, wherein the reference treatment is identical to the treatment, except that the molar ratio between ATIII to Factor II of the product used in said reference treatment is below 1:30.

7. The use according to any one of claims 1-6, wherein the value of time to hemostasis of the patient following the treatment with the product is:

i) decreased compared to the value of time to hemostasis following placebo treatment or without treatment, and/or

ii) decreased by at least 25%, at least 30%, at least 35%, at least 40%, at least 45%, at least 50%, at least 55% or at least 60% compared of the value following placebo treatment or of the value without treatment.

8. The use according to any one of claims 1-7, wherein the value of time to hemostasis of the patient following the treatment with the product is:

i) either essentially identical or only moderately increased when compared to a reference treatment, or

ii) decreased when compared to a reference treatment, or

iii) decreased compared to a value following a reference treatment by at least 5%, by at least 10%, by at least 15% or by at least 20%, wherein the reference treatment is identical to the treatment, except that the molar ratio between ATIII to Factor II of the product used in the reference treatment is below 1:30.

9. The use according to any one of claims 1-8, wherein in case of the value of time to hemostasis of the patient following the treatment with the product is only moderately increased when compared to a reference treatment, the moderate increase of the value amounting to not more than 80%, not more than 70%, not more than 60%, not more than 50%, not more than 40%, not more than 30%, not more than 20% or not more than 10%, wherein the reference treatment is identical to the treatment, except that the molar ratio between ATIII to Factor II of the product used in the reference treatment is below 1:30.

10. The use according to any one of claims 1-9, wherein the value of prothrombin time (PT) and/or the value of activated partial thromboplastin time (aPTT) of the patient following treatment with the product is decreased compared to the value of prothrombin time (PT) and/or the value of activated partial thromboplastin time (aPTT) of a reference treatment by a factor of at least 1.5, at least 2.0, at least 2.5, at least 3.0, at least 3.5, at least 4.0, at least 4.5, at least 5.0, at least 7, or at least 10, wherein the reference treatment is identical to the treatment, except that the molar ratio between ATIII to Factor II of the product used in the reference treatment is below 1:30.

11. The use according to any one of claims 1-10, wherein the value of prothrombin time (PT) and/or the value of activated partial thromboplastin time (aPTT) of the patient following treatment with the product is essentially identical and/or has a maximum deviation of the value when compared to the respective value of prothrombin time (PT) and/or the respective value of activated partial thromboplastin time (aPTT) following placebo treatment or without treatment, provided that the maximum deviation does not exceed a factor of 5.0, of 3.0, of 2.5, of 2.0, or of 1.5.

12. The use according to any one of claims 1-11, wherein:

i) the value of thrombin generation of the patient following treatment with the product is reduced when compared to a value of thrombin generation of a reference treatment by at least 5%, by at least 10%, by at least 15%, by at least 20%, by at least 25%, by at least 30%, by at least 35%, by at least 40%, by at least 45% or by at least 50%, wherein said reference treatment is identical to the treatment, except that the molar ratio between ATIII to Factor II of the product used in the reference treatment is below 1:30, or

ii) the value of Endogenous Thrombin Potential (ETP) of the patient following treatment with the product is reduced when compared to a value of the ETP of a reference treatment by at least 5%, by at least 10%, by at least 15%, by at least 20%, by at least 25%, by at least 30%, by at least 35%, by at least 40%, by at least 45% or by at least 50%, wherein the reference treatment is identical to the treatment, except that the molar ratio between ATIII to Factor II of the product used in the reference treatment is below 1:30.

13. The use according to any one of claims 1-12, wherein the value of D-Dimer concentration (DD) of the patient's blood following treatment with the product is reduced compared to a reference treatment by a factor of at least 2, at least 3, at least 4, at least 5, at least 7, or at least 10, wherein the reference treatment is identical to the treatment, except that

the molar ratio between ATIII to Factor II of the product used in said reference treatment is below 1:30.

14. The use according to any one of claims 1-13, wherein the product further comprises heparin and/or albumin.

15. The use according to any one of claims 1-14, wherein the Factor II is provided within the product with an activity level of:

i) between 10 – 80 IU/mL, or

ii) between 15 – 60 IU/mL.

16. The use according to any one of claims 1-15, wherein the molar ratio between ATIII to Factor II is not higher than 1 : 0.5 or 1:1.

17. The use according to any one of claims 1-16, wherein the molar ratio between ATIII to Factor II is within a range:

i) between 1:25 to 1:0.5, or

ii) between 1:25 to 1:1.

18. The use according to any one of claims 1-17, wherein the treatment or prophylaxis comprises treatment and perioperative prophylaxis of bleedings in:

i) acquired deficiency of the prothrombin complex coagulation factors,

ii) a deficiency caused by treatment with vitamin K antagonists,

iii) a case of overdose of vitamin K antagonists, when rapid correction of the deficiency is required,

iv) a congenital deficiency of any vitamin K dependent coagulation factor, and/or

v) a congenital deficiency of any vitamin K dependent coagulation factor when purified specific coagulation factor products are not available.

19. The use according to any one of claims 1-18, wherein in addition to the treatment with the product, the patient is in advance, simultaneously or subsequently treated with a replacement product, a cryoprecipitate, or a fibrinogen concentrate.

20. The use according to claim 20, wherein the fibrinogen concentrate is to be administered at a fibrinogen amount in a range between 5 mg/kg and 150 mg/kg bodyweight, between 10 mg/kg and 100 mg/kg bodyweight, or between 20 mg/kg and 80 mg/kg bodyweight.

21. The use according to any one of claims 2-20, wherein the product is a prothrombin complex concentrate (PCC) of either one of the following two types:

i) a 3-factor complex comprising factors II, IX and X; or 15

ii) a 4-factor complex additionally comprising factor VII.