NovoSeven®
Recombinant Factor VIIa

Recipient's name Recipient's Title
Recipient's address
City, Post Code

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Local Brand Manager
Novo Nordisk address
City, Post Code

January, 2022

Women with Glanzman's thrombasthenia (GT)† and CFVIId face additional challenges due to Heavy Menstrual Bleeding*[1]

Heavy menstrual bleeding affects **92 %** of women with severe cFVIID[2]

Up to **98 %** of women with GT[3]

Dear Healthcare Professional,

Women with severe congenital factor VII deficiency (cFVIID) or Glanzmann's thrombasthenia (GT) are likely to suffer from Heavy Menstrual Bleeding.[2,3]

Despite this high prevalence, a recent survey of European haemophilia treatment centres revealed that few patients present for treatment.[4]

Without intervention, Heavy Menstrual Bleeding can have negative impacts to patients' lives, including reduced quality of life, absenteeism from work and school, and iron-deficiency anaemia, making prompt treatment vital.[5,6]

NovoSeven® permits prompt treatment at home for patients trained to self-infuse, which can reduce the disruption to school, work and family life for patients.[7]

For further information on NovoSeven®, please contact [insert Novo Nordisk representative details].

Yours sincerely,
[insert name and details]

Success speaks for itself.[8-25]

†GT indication in patients with past or present refractoriness to platelet transfusions, or where platelets are not readily available
*GT and cFVIId to stay on label since this is promotional
Please refer to the NovoSeven® Summary of Product Characteristics for full prescribing information.

novo nordisk®

References
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Abbreviated Summary of Product Characteristics

NovoSeven® 1 mg (50 KIU) powder and solvent (vial or pre-filled syringe) for solution for injection.
NovoSeven® 2 mg (100 KIU) powder and solvent (vial or pre-filled syringe) for solution for injection. NovoSeven® 5 mg (250 KIU) powder and solvent (vial or pre-filled syringe) for solution for injection. NovoSeven® 8 mg (400 KIU) powder and solvent (vial or pre-filled syringe) for solution for injection. ***Composition:*** eptacog alfa (activated), eptacog alfa (activated) is recombinant coagulation factor VIIa (rFVIIa) produced in baby hamster kidney cells (BHK Cells) by recombinant DNA technology, 1 mg/vial, 2 mg/vial, 5 mg/vial, 8 mg/vial (corresponds to 50 KIU/vial, 100 KIU/vial, 250 KIU/vial, 400 KIU/vial). 1mg/ml eptacog alfa (activated) after reconstitution.
List of excipients: Powder: Sodium chloride, Calcium chloride dihydrate, Glycylglycine, Polysorbate 80, Mannitol, Sucrose, Methionine, Hydrochloric acid, Sodium hydroxide ***Solvent:*** Histidine, Hydrochloric acid, Sodium hydroxide, Water for injections. ***Indications:*** treatment of bleeding episodes and prevention of bleeding in those undergoing surgery or invasive procedures in the following patient groups:
- patients with congenital haemophilia with inhibitors to coagulation factors VIII or IX
- >5 BU;
- patients with congenital haemophilia who are expected to have a high anamnestic
- response to factor VIII or factor IX administration;
- patients with acquired haemophilia;
- patients with congenital FVII deficiency;
- patients with Glanzmann's thrombasthenia with past or present refractoriness to platelet transfusions, or where platelets are not readily available.

Posology: ***Haemophilia A or B with inhibitors or expected to have a high anamnestic response:***
Mild to moderate bleeding episodes (includ
has been shown to be efficacious in the treat
and mucocutaneous bleeds. Two dosing regi
three injections of 90 µg per kg body weight
further treatment is required, one additional
be administered 2) One single injection of 27
of the home therapy should not exceed 24 ho
administration of a single dose of 270 µg per k
Serious bleeding episodes: An initial dose of 90 µg per kg body weight is recommended and could be administered on the way to the hospital where the patient is usually treated. The following dose varies according to the type and severity of the haemorrhage. Dosing frequency should initially be every second hour until clinical improvement is observed. If continued therapy is indicated, the dose interval can then be increased to 3 hours for 1 – 2 days. Thereafter, the dose interval can be increased successively to every 4, 6, 8 or 12 hours for as long as treatment is judged as being indicated. A major bleeding episode may be treated for 2 – 3 weeks but can be extended beyond this if clinically warranted.
Invasive procedure/surgery: An initial dose of 90 µg per kg body weight should be given immediately before the intervention. The dose should be repeated after 2 hours and then at 2 – 3 hour intervals for the first 24 – 48 hours depending on the intervention performed and the clinical status of the patient. In major surgery, the dose should be continued at 2 – 4 hour intervals for 6 – 7 days. The dose interval may then be increased to 6 – 8 hours for another 2 weeks of treatment. Patients undergoing major surgery may be treated for up to 2 – 3 weeks until healing has occurred. ***Acquired Haemophilia:*** NovoSeven® should be given as early as possible after the start of a bleeding episode. The recommended initial dose, administered by intravenous bolus injection, is 90 µg per kg body weight. Following the initial dose of NovoSeven® further injections may be given if required. The duration of treatment and the interval between injections will vary with the severity of the haemorrhage, the invasive procedures or the surgery being performed. The initial dose interval should be 2 – 3 hours. Once haemostasis has been achieved, the dose interval can be increased successively to every 4, 6, 8 or 12 hours for as long as treatment is judged to be indicated. ***Factor VII deficiency:*** The recommended dose range is 15 – 30 µg per kg body weight every 4 – 6 hours until haemostasis is achieved. Dose and frequency of injections should be adapted to each individual. Limited clinical experience in long term prophylaxis in paediatric population has been gathered in the paediatric population below 12 years of age, with a severe clinical phenotype. Dose and frequency of injections for prophylaxis should be based on clinical response and adapted to each individual. ***Glanzmann's thrombasthenia:*** The recommended dose is 90 µg (range 80 – 120 µg) per kg body weight at intervals of two hours (1.5 – 2.5 hours). At least three doses should be administered to secure effective haemostasis. The recommended route of administration is bolus injection as lack of efficacy may appear in connection with continuous infusion. For those patients who are not refractory, platelets are the first line treatment for Glanzmann's thrombasthenia. ***Contraindications:*** Hypersensitivity to the active substance, or to any of the excipients, or to mouse, hamster or bovine protein. ***Interaction with other medicinal products and other forms of interaction:*** The risk of a potential interaction between NovoSeven® and coagulation factor concentrates is unknown. Simultaneous use of prothrombin complex concentrates, activated or not, should be avoided. Anti-fibrinolytics have been reported to reduce blood loss in association with surgery in haemophilia patients, especially in orthopaedic surgery and surgery in regions rich in fibrinolytic activity, such as the oral cavity. Experience with concomitant administration of anti-fibrinolytics and rFVIIa treatment is however limited. Based on a non-clinical study it is not recommended to combine rFVIIa and rFXIII. There are no clinical data available on interaction between rFVIIa and rFXIII. ***Undesirable effects:*** The most frequent adverse drug reactions (ADR) are pyrexia and rash (uncommon: > 1/1,000 to < 1/100), and the most serious adverse drug reactions are thromboembolic events. The frequency is classified as: Uncommon (≥1/1,000 to <1/100), Rare (≥1/10,000 to <1/1,000) or Not Known. The frequencies of both serious and non-serious adverse drug reactions are listed by system organ class: Blood and lymphatic system disorders: ***Rare:*** Disseminated intravascular coagulation, related laboratory findings, including elevated levels of D-dimer and decreased levels of Anti Thrombin (AT) and coagulopathy. Gastrointestinal disorders: ***Rare:*** nausea. General disorders and administration site conditions: ***Uncommon:*** ADRs are decreased therapeutic response and pyrexia. ***Rare:*** ADR is injection site reaction including injection site pain. Immune system disorders: Hypersensitivity is ***Rare***; anaphylactic reaction frequency is ***not known***. Investigations: ***Rare:*** increased fibrin degradation products, increase of alanine aminotransferase, alkaline phosphatase, lactate dehydrogenase and prothrombin. Nervous system disorders: ***Rare:*** headache, skin and subcutaneous tissue disorders: ***Uncommon:*** Rash (including allergic dermatitis and rash erythematous), pruritus and urticaria. Unknown frequency: flushing and angioedema. Vascular disorders: ***Uncommon:*** venous thromboembolic events (deep vein thrombosis, thrombosis at i.v. site, pulmonary embolism, thromboembolic events of the liver including portal vein thrombosis, renal vein thrombosis, thrombophlebitis, superficial thrombophlebitis and intestinal ischaemia). ***Rare:*** Arterial thromboembolic events (myocardial infarction, cerebral infarction, cerebral ischaemia, cerebral artery occlusion, cerebrovascular accident, renal artery thrombosis, peripheral ischaemia, peripheral arterial thrombosis and intestinal ischaemia), Angina pectoris. ***Unknown:*** Intracardiac thrombus. ***Inhibitory antibodies:*** In post-marketing experience, there have been no reports of inhibitory antibodies against NovoSeven® or FVII in patients with haemophilia A or B. In factor VII deficiency clinical trials: formation of antibodies against NovoSeven® and FVII is the only ADR reported (common). Development of inhibitory antibodies to NovoSeven® has been reported in a post-marketing observational registry of patients with congenital FVII deficiency. ***Reporting of suspected adverse reactions*** after authorisation of the medicinal product is important. It allows continued monitoring of
al product. ***Overdose:*** Four cases of overdose
aemophilia in 16 years. The only complication
ose was a slight transient increase in blood
ng 24 mg rFVIIa instead of 5.5 mg. No cases of
ts with acquired haemophilia or Glanzmann's
VII deficiency, where the recommended dose is
erdose has been associated with a thrombotic
0 year) male patient treated with 10 – 20 times
n, the development of antibodies against NovoSeven® and FVII has been associated with overdose in one patient with factor VII deficiency. The dose schedule should not be intentionally increased above the recommended doses due to the absence of information on the additional risk that may be incurred. **Administration:** NovoSeven® (eptacog alfa activated) is administered intravenously over 2 – 5 minutes. **Caution:** Some needleless connectors with an internal spike used with central venous access devices (CVADs) may be incompatible with the pre-filled glass syringe and prevent administration. Therefore, use of an alternative sterile 10ml luer-lock plastic syringe may be required for withdrawal and injection of the reconstituted solution. Follow the instructions for use for the CVAD and needleless connector. **Storage:** 3 years shelf life when product is stored below 25°C. Store powder and solvent below 25°C and protect from light. Do not freeze. After reconstitution, chemical and physical stability has been demonstrated for 6 hours at 25°C and 24 hours at 5°C. It is recommended the product be used immediately after reconstitution. If not used immediately, storage time and storage conditions prior to use are the responsibility of the user, and should not be longer than 24 hours at 2°C – 8°C, unless reconstitution has taken place in controlled and validated aseptic conditions. The reconstituted solution should be stored in the vial. ***Way of delivery:*** Medical prescription. ***Authorisation holder:*** Novo Nordisk A/S, Bagsvaerd, Denmark. ***Date of last revision SMPC:*** November 2020. **For more detailed information please consult the EMEA product information.** Novo Nordisk® is a registered trademark owned by Novo Nordisk A/S. NovoSeven® is a registered trademark owned by Novo Nordisk Health Care AG, The Circle 32/38, 8058 Zurich, Switzerland.

Please update this abbreviated summary of products characteristics with local product information

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