The NovoEight® Abbreviated Prescribing Information (aPI) is based on the EUSmPC as of November 2020 .Registration conditions differ internationally. Always refer to the full local SmPC before prescribing. NovoEight® is registered in the USA, EU and Japan

This Abbreviated Prescribing Information (API) reflects SmPC version as of October 2020
Were changes done to this API as a result of the SmPC change above? YES☐ NO☒

Prepared and updated by Global Medical Affairs Biopharm based on EU SmPC
Date: October 2020
VEEVA PROMOMATS ID: HQ20NEGT00013
Reviewed: November 2020

Abbreviated Prescribing Information, NovoEight®

NovoEight 250 IU powder and solvent for solution for injection
NovoEight 500 IU powder and solvent for solution for injection
NovoEight 1000 IU powder and solvent for solution for injection
NovoEight 1500 IU powder and solvent for solution for injection
NovoEight 2000 IU powder and solvent for solution for injection
NovoEight 3000 IU powder and solvent for solution for injection

Composition Turoctocog alfa is recombinant coagulation factor VIII (rFVIII) produced in Chinese hamster ovary (CHO) cells by recombinant DNA technology. NovoEight 250 IU contains approximately 62.5 IU/ml, 500 IU contains 125 IU/ml, 1000 IU contains 250 IU/ml, 1500 IU contains 375 IU/ml, 2000 IU contains 500 IU/ml and 3000 IU contains 750 IU/ml turoctocog alfa after reconstitution. Excipient with known effect: 30.5 mg sodium per reconstituted vial.
Therapeutic indications Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency). NovoEight can be used for all age groups.
Posology and method of administration
Appropriate determination of factor VIII levels is advised to guide the dose to be administered and the frequency of repeated injections. Individual patients may vary in their response to factor VIII, demonstrating different half-lives and recoveries. Dose based on bodyweight may require adjustment in underweight or overweight patients.
On demand treatment: Required units = body weight (kg) x desired factor VIII rise (%) (IU/dl) x 0.5 (IU/kg per IU/dl).
Early haemarthrosis, muscle bleeding or oral bleeding: FVIII level required (%) (IU/dl): 20-40, repeat every 12-24 hours, at least 1 day. More extensive haemarthrosis, muscle bleeding or haematoma: FVIII level required (%) (IU/dl): 30-60, Repeat infusion every 12-24 hours for 3-4 days or more.
Life threatening haemorrhages: FVIII level required (%) (IU/dl):60-100, repeat every 8-24 hours until threat is resolved.
Surgery: Minor surgery incl. tooth extraction: FVIII level required (%) (IU/dl): 30-60, every 24 hours, at least 1 day, until healing is achieved. Major surgery: FVIII level required (%) (IU/dl): 80-100, Repeat infusion every 8-24 hours until adequate wound healing, then therapy for at least another 7 days to maintain a factor VIII activity of 30-60 (IU/dl).
Prophylaxis – adults and children above 12 years: The recommended doses are 20-40 IU/kg every second day or 20-50 IU/kg 3 times weekly. In some cases (younger patients) shorter dosage intervals/higher doses may be necessary. Less frequent regimen (40-60 IU/kg every third day or twice weekly) may be applicable.
Prophylaxis – children below 12 years: In patients below the age of 12, doses of 25-50 IU/kg every second day or 25-60 IU/kg 3 times weekly are recommended.
Method of administration *Intravenous use.* The recommended infusion rate for NovoEight is 1-2 ml/min.
Contraindications Hypersensitivity to the active substance, or to any of the excipients, or known allergic reaction to hamster proteins.
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Special warnings and precautions for use
Traceability
The name and the batch number of the administered product should be clearly recorded to improve traceability of biological medicinal products.
Hypersensitivity: Allergic type hypersensitivity reactions are possible with NovoEight. The product contains traces of hamster proteins, which in some patients may cause allergic reactions. If symptoms of hypersensitivity occur, patients should be advised to discontinue use of the medicinal product immediately and contact their physician. Patients should be informed of the early signs of hypersensitivity reactions including hives, generalised urticaria, tightness of the chest, wheezing, hypotension and anaphylaxis. In case of shock, standard medical treatment for shock should be implemented.
Inhibitors: The formation of neutralising antibodies (inhibitors) to factor VIII is a known complication in the management of individuals with haemophilia A. The risk of developing inhibitors is correlated to the severity of the disease as well as the exposure to factor VIII, this risk being highest within the first 50 exposure days but continues throughout life although the risk is uncommon. The clinical relevance of inhibitor development will depend on the titre of the inhibitor, with low titre posing less of a risk of insufficient clinical response than high titre inhibitors. In general, all patients treated with coagulation factor VIII products should be carefully monitored for the development of inhibitors by appropriate clinical observation and laboratory test. If the expected factor VIII activity plasma levels are not attained, or if bleeding is not controlled with an appropriate dose, testing for factor VIII inhibitor presence should be performed. In patients with high levels of inhibitor, factor VIII therapy may not be effective and other therapeutic options should be considered. Management of such patients should be directed by physicians with experience in the care of haemophilia and factor VIII inhibitors.
Cardiovascular event: In patients with existing cardiovascular risk factors, substitiution therapy with FVIII may increase the cardiovascular risk
Catheter-related complications: If a central venous access device (CVAD) is required, risk of CVAD-related complications including local infections, bacteraemia and catheter site thrombosis should be considered.
It is strongly recommended that every time NovoEight is administered to a patient, the name and batch number of the product are recorded, in order to maintain a link between the patient and the batch of the medicinal product.
Paediatric population: The listed warnings and precautions apply both to adults and children.
Excipient related considerations: The medicinal product contains 30.5 mg sodium per reconstituted vial, equivalent to 1.5% of the WHO recommended maximum daily intake of 2 g sodium for an adult.
Undesirable effects: PTPs - common (≥1/100 to <1/10): Hepatic enzymes increased, injection site reactions, Incorrect dose administered. Uncommon (≥ 1/1,000 to < 1/100): FVIII inhibition, insomnia, headache, dizziness, burning sensation, sinus tachycardia, acute myocardial infarction, hypertension, lymphoedema, hyperaemia, rash, lichenoid keratosis, skin burning sensation, musculoskeletal stiffness, arthropathy, pain in extremity, musculoskeletal pain, fatigue, feeling hot, oedema peripheral, pyrexia, heart rate increased, contusion. **PUPs** - very common: (≥1/10) FVIII inhibition; common (≥1/100 to <1/10): flushing, thrombophlebitis superficial, rash, rash erythematous, haemarthrosis, muscle haemorrhage, cough, pyrexia, catheter site erythema, anti factor VIII antibody positive, vomitting, infusion related reaction, thrombosis in the device. **Shelf life:** *Unopened* 30 months when stored in a refrigerator (2°C – 8°C). During the shelf life, the product may be kept at room temperature (≤ 30°C) no for a single period longer than 9 months or above room temperature (30°C up to 40°C) for a single period no longer than 3 months. *After reconstitution* 24 hours stored at 2°C – 8°C, or 4 hours stored at 30°C for product kept for a single period no longer than 9 months at ≤30°C, or 4 hours stored up to 40°C, for product kept for a single period no longer than 3 months at 30°C up to 40°C
Way of delivery*:* Prescription-only medicine. Please refer to local prescribing information for full details.
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Date of last revision November 2020
For more detailed information please consult the EMA product information.

HQ20NEGT00013