Prescribing Information for ▼Nuwiq® (human coagulation factor VIII (rDNA), simoctocog alfa). Please refer to the Summary of Product Characteristics before prescribing.

Presentation: Powder and solvent for solution for injection. Each vial contains either 250 or 500 or 1000 or 2000 IU simoctocog alfa. Solvent is 2.5 mL of sterilised water in a prefilled syringe.
Indications: Treatment and prophylaxis of bleeding in paediatric and adult patients with haemophilia A (congenital factor VIII deficiency).
Dosage and administration: Treatment should be under the supervision of a physician experienced in the treatment of haemophilia.
On-demand treatment: The required dose is determined using the following formula: Required units = body weight (kg) x desired factor VIII rise (%) (IU/dL) x 0.5
Prophylaxis: 20-40 IU/kg at 2 to 3 day intervals. In some cases shorter dosage intervals or higher doses may be necessary.
Paediatric population: Efficacy and safety in children less than two years of age have not been established.
Previously untreated patients: Safety and efficacy have not yet been established.
Method of administration: For intravenous use. Recommended rate ≤4 mL/min.
Contraindications: Hypersensitivity to the active substance or to any of the excipients.
Precautions and Warnings:
Hypersensitivity: Allergic type hypersensitivity reactions are possible. If symptoms occur, patients should be advised to discontinue use immediately and contact their physician. Inform patients of early signs of hypersensitivity. In case of shock, standard medical treatment for shock should be implemented.
Inhibitors: Monitor patients treated with factor VIII products for inhibitor development by clinical observations and laboratory tests. Risk of developing inhibitors is correlated to exposure to Factor VIII: risk is highest in first 20 exposure days.
Catheter-related complications: If a central venous access device (CVAD) is required, consider risk of CVAD-related complications. It is strongly recommended that every time Nuwiq® is administered, the name and batch number of the product are recorded.
Fertility, pregnancy and lactation: Experience regarding use of factor VIII during pregnancy and breast feeding is not available. There are no fertility data available.
Undesirable effects: No common side effects lised. Serious potential side effects include anaphylactic shock or development of neutralising antibodies. Other potential side effects include hypersensitivity reactions, parasthesia, headache, vertigo, dry mouth, back pain, injection site inflammation, injection site pain, non-neutralising anti-factor VIII antibody positive. Prescribers should consult the Summary of Product Characteristics for further information about adverse reactions.
Legal category: POM.

Market Authorisation Numbers and NHS price:
250 IU (EU/1/14/936/001) - £190 per vial
500 IU (EU/1/14/936/002) - £380 per vial
1000 IU (EU/1/14/936/003) - £760 per vial
2000 IU (EU/1/14/936/004) - £1,520 per vial
Marketing Authorisation Holder: Octapharma AB, Lars Forssells gata 23, 112 75 Stockholm, Sweden.
UK Supplier: Octapharma Limited, 26 Spring Gardens, Manchester M2 1AB, UK.
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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Octapharma by telephoning 0845 1300 522.