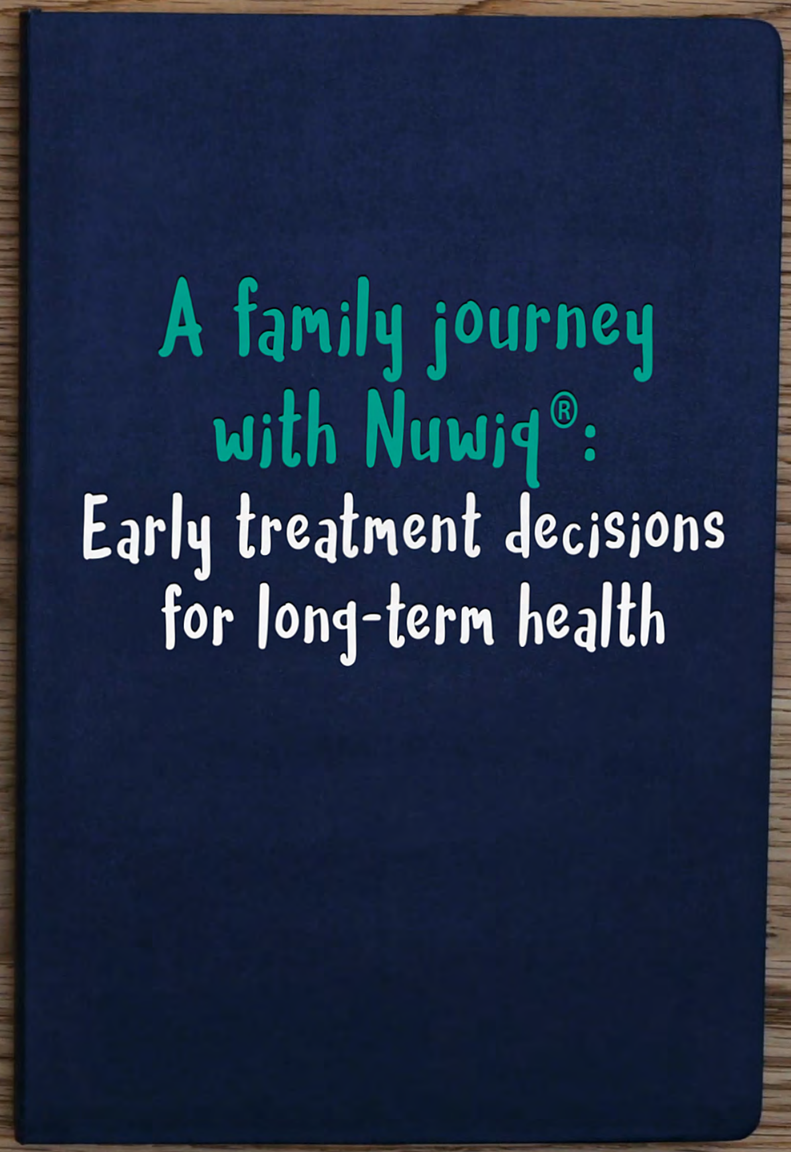
Nuwiq®
Antihemophilic Factor
(Recombinant)

FOR HEALTHCARE PROFESSIONALS ONLY

EAHAD 2021
VIRTUAL CONGRESS
3–5 February 2021



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Antihemophilic Factor
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SPEAKERS

ROBERT F. SIDONIO, MD
Children's Heathcare of
Atlanta, Emory University, US

MARY MATHIAS, MD
Great Ormond Street
Hospital, UK

CARMEN ESCURIOLA, MD
Haemophilia Center
Rhein Main, DE

SANDER BOTTER, PhD
Balgrist Campus AG
Zurich, CH

AGENDA

A family journey with Nuwiq®:
Early treatment decisions for long-term health

THURSDAY, 4 FEBRUARY 2021, 18:00 - 19:00 CET

Chair: Robert F. Sidonio	Welcome and introduction
Mary Mathias	NuProtect study: Making informed treatment decisions in your PUPs
Carmen Escuriola	Unlocking opportunities in your inhibitor patients
Sander Botter	A joint effort: understanding the role of FVIII beyond haemostasis
All	LIVE Q&A

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Nuwiq® (human coagulation factor VIII, simoctocog alfa) Abbreviated Product Information
POWDER AND SOLVENT FOR SOLUTION FOR INJECTION

Please refer to the Summary of Product Characteristics before prescribing.

Presentation: Each vial of Nuwiq powder and solvent for solutions for injection contains 250, or 500, or 1000, or 2000, or 2500, or 3000, or 4000 IU simoctocog alfa. Solvent: 2.5 ml water for injections in a prefilled glass syringe. **Indication**: Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency). Nuwiq can be used for all age groups. **Dosage:** Treatment should be under the supervision of a physician experienced in the treatment of haemophilia. During the course of treatment, appropriate determination of factor VIII levels is advised to guide the dose to be administered and the frequency of repeated infusions. The dose and duration of the therapy depend on the severity of the factor VIII deficiency, on the location and extent of the bleeding and on the patient's clinical condition. Dose based on bodyweight may require adjustment in underweight or overweight patients. For full details of dosing recommendations, refer to the SPC. 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 (IU/kg per IU/dl). Prophylaxis: Usual doses are 20 to 40 IU per kg body weight at intervals of 2 to 3 days. **Individualised prophylaxis:** Individualised PK-based prophylaxis was evaluated in 66 adult PTPs with severe haemophilia A. Following a 1-3 month standard prophylaxis phase (every other day or 3 times weekly dosing), 44 (67%) patients were switched to a dosing regimen based on their PK assessment, and 40 completed the 6 months of prophylaxis according to the assigned dosing and treatment scheme. Of these patients, 34 (85%) were treated twice weekly or less. 33 (82.5%) patients did not experience any bleeds and 36 (90.0%) patients had no spontaneous bleeds. The mean ± SD annualised bleeding rate was 1.2 ± 3.9 and the mean ± SD dose were 52.2 ± 12.2 IU/kg per injection and 99.7 ± 25.6 IU/kg per week. Paediatric population: Dosing is the same in adults and children and adolescents, but shorter dose intervals or higher doses may be necessary for children and adolescents. **Administration:** For intravenous use (recommended administration no more than 4 ml per minute).

Contraindications: Hypersensitivity to the active substance or to any of the excipients. **Special Warnings and Precautions:** 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: Carefully monitor patients treated with factor VIII products for the development of inhibitors by clinical observations and laboratory tests. Cardiovascular events: In patients with existing cardiovascular risk factors, therapy with factor VIII may increase the cardiovascular risk. Catheter-related complications: If a central venous access device (CVAD) is required, consider risk of CVAD-related complications. Excipient related considerations: Nuwiq contains less than 1 mmol sodium (23 mg) per vial. To be taken into consideration by patients on a controlled sodium diet. Traceability: It is strongly recommended that every time Nuwiq is administered to a patient, the name and batch number of the product are recorded. **Interactions:** No interaction studies have been performed. **Fertility, Pregnancy and Lactation:** Experience regarding use of factor VIII during pregnancy and breast feeding is not available. Nuwiq should be used during pregnancy and breast feeding only if clearly indicated. There are no fertility data available. **Undesirable Effects:** very common (>1/10): factor VIII inhibition in Previously Untreated Patients; common (>1/100 to <1/10): hypersensitivity, pyrexia; uncommon (>1/1000 to <1/100): haemorrhagic anaemia, factor VIII inhibition in Previously Treated Patients (PTPs), paraesthesia, headache, vertigo, dry mouth, back pain, injection site inflammation, injection site pain, non-neutralising antibody positive (PTPs). Prescribers should consult the SPC for further information about adverse reactions. **Storage:** Store in a refrigerator (2-8°C). Do not freeze. Protect from light. Keep the reconstituted solution at room temperature and use immediately. Do not refrigerate after reconstitution. **Legal Classification:** Subject to medical prescription (POM). **Pack Sizes and Basic Cost:** Country specific. **Marketing Authorisation Holder:** Octapharma AB, Lars Forssells gata 23, 112 75 Stockholm, Sweden. **Marketing Authorisation Numbers:** EU/1/14/936/001, /002, /003, /004, /005, /006, /007. **Date of Preparation:** December 2020, Octapharma AG, Seidenstrasse 2, 8853 Lachen, Switzerland.

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