This symposium is for healthcare professionals only

Conveniently Protecting What Matters: Nuwiq® (Simoctocog Alfa) in PUPs and Personalised Prophylaxis*

Monday, 8 July 2019
13:15 – 14:30
Location: Melbourne Room 2
ISTH 2019, Melbourne

Chair: Ellis J. Neufeld, USA
Speakers: Robert Klamroth, Germany
Georgina W. Hall, United Kingdom
Carmen Escuriola Ettingshausen, Germany
Ri Liesner, United Kingdom

* Nuwiq® is not approved for use in PUPs and personalised prophylaxis in Australia.
Please review product information before prescribing.
Product Information is available at the Octapharma booth.
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Chair: Ellis J. Neufeld, USA

13:15 **Welcome and Introduction**
Ellis J. Neufeld, USA

13:20 **The Potential of Personalised Prophylaxis: Optimising Treatment with Nuwiq®**
Robert Klamroth, Germany

13:35 **Real-world Experience with Nuwiq® for Inhibitor Management**
Georgina W. Hall, United Kingdom

13:45 **Inhibitor Management in the Context of New Therapies for Haemophilia A: The MOTIVATE Study**
Carmen Escuriola Ettingshausen, Germany

14:00 **NuProtect study: Final Data with Nuwiq® in PUPs with Haemophilia A**
Ri Liesner, United Kingdom

14:15 **Q&A**
All

14:25 **Conclusions**

FVIII treatment continues to adapt to better meet the needs of individuals with haemophilia A. Experience with Nuwiq®, both from clinical studies and in the real-world setting, continues to demonstrate its favourable immunogenicity profile and effective bleeding protection, especially when the treatment regimen is personalised. As the haemophilia treatment landscape evolves, it is critical that we understand the role of FVIII replacement in the context of novel therapeutic approaches. Findings from the MOTIVATE study will have the potential to inform important treatment decisions for patients with inhibitors and increase our understanding of the importance of FVIII. In this session we will discuss the growing data for Nuwiq® and consider the role of FVIII in the management of haemophilia A patients with and without inhibitors, now and in the future.

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 pre-filled 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. 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 day. Paediatric population: Dosing is the same in adults and children, but shorter dose intervals or higher doses may be necessary for children. **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. 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:** October 2018, Octapharma AG, Seidenstrasse 2, 8853 Lachen, Switzerland.

Nuwiq® is not listed in the PBS.
Nuwiq® is not currently supplied in Australia.

Date of preparation: May 2019
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