Building on the standard of care: Latest innovation in FVIII

Wednesday, February 6, 2019 | 15:30–16:45
Level 2, Forum Hall, Prague Congress Centre

15:30  Welcome and introductions
Elena Santagostino (chair)
University of Milan, Italy

15:35  Moving forward together: growing patient aspirations and the evolution of FVIII in hemophilia A
Robert Klamroth
Vivantes Klinikum im Friedrichshain, Berlin, Germany

16:00  Meeting patients’ aspirations: Jivi® in the clinical setting
Mark Reding
University of Minnesota, USA

16:25  The patient perspective on Jivi®: 6 years and counting
Erik Beckers & patient
Maastricht UMC, Netherlands

16:35  Q&A and close
Elena Santagostino
University of Milan, Italy

Jivi® abridged SmPC is available on page 2
MA-JIV-ALL-0013-1 | MA-JIV-CZ-0003-1 | 12/2018
This Abridged SmPC is in accordance with the registration of the product in the EU. The Summary of Product Characteristic may vary from other countries in which the product is approved. The product also may not be approved for use in all countries. Please contact your local Bayer affiliate for the product information applicable to your country.

This medicinal product is subject to additional monitoring This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.


Indication: Treatment and prophylaxis of bleeding in previously treated patients ≥ 12 years of age with haemophilia A (congenital factor VIII deficiency). Administration and Dosage: Treatment must be under the supervision of a physician experienced in the treatment of haemophilia. Dosage regimens and routes of administration: The calculation of the required dose of factor VIII is based on the empirical finding that 1 IU factor VIII per kg body weight raises the plasma factor VIII activity by 1.5 – 2.5 % of normal activity. For exact calculation of dosage, please read carefully the complete product information. Jivi is for intravenous use.

Contraindications: Hypersensitivity to the active substance or to any of the excipients. Known allergic reactions to mouse or hamster proteins. Warnings and Precautions: Allergic type hypersensitivity reactions are possible. Hypersensitivity reactions could also be related to antibodies against polyethylene glycol (PEG). If symptoms of hypersensitivity occur, patients should be advised to discontinue the use of the medicinal product immediately and contact their physician. Patients should be informed of the early signs of hypersensitivity reactions including hives, generalized urticaria, tightness of the chest, wheezing, hypotension, and anaphylaxis. Symptomatic treatment for hypersensitivity should be instituted as appropriate. The formation of neutralising antibodies (inhibitors) to FVIII is a known complication in the management of individuals with haemophilia A. 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. A clinical immune response associated with anti-PEG antibodies, manifested as symptoms of acute hypersensitivity and/or loss of drug effect has been observed primarily within the first 4 exposure days. In patients with existing cardiovascular risk factors, substitution therapy with factor VIII may increase the cardiovascular risk. 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. Fertility, pregnancy and lactation: Animal reproduction studies have not been conducted with factor VIII. Based on the rare occurrence of haemophilia A in women, experience regarding the use of factor VIII during pregnancy and breastfeeding is not available. Therefore, factor VIII should be used during pregnancy and breast-feeding only if clearly indicated. In the repeat dose systemic toxicity studies in rats and rabbits with Jivi, treatment related effects on male reproductive organs were not seen. The effect on fertility in humans is unknown. Interactions: Interactions of human coagulation factor VIII (rDNA) products with other medicinal products have not been reported. Undesirable effects: very common: headache; common: hypersensitivity, insomnia, dizziness, cough, abdominal pain, nausea, vomiting, erythema (incl. erythema and erythema multiforme), rash (incl. rash and rash popular), injection site reactions (incl. injection site pruritus/rash and vessel puncture site pruritus), pyrexia; uncommon: FVIII inhibition (previously treated patients), dysgeusia, flushing, pruritus.

Storage conditions: Store in a refrigerator (2 °C ¬ 8 °C). Do not freeze. Keep the vial and the pre-filled syringe in the outer carton in order to protect from light. Within its overall shelf-life of 2 years, the product (when kept in its outer carton) may be stored at up to 25 °C for a limited period of 6 months. This date should never exceed the expiry date printed on the outer carton. At the end of this period the product should not be put back in the refrigerator, but should be used or discarded. The chemical and physical in-use stability after reconstitution has been demonstrated for 3 hours at room temperature. Do not refrigerate after reconstitution. From a microbiological point of view the product should be used immediately after reconstitution. If not used immediately, the in-use storage times and conditions prior to use are the responsibility of the user.

Marketing Authorisation Holder: Bayer AG, 51368 Leverkusen, Germany. Registration number: EU/1/18/1324/001 (250 IU); EU/1/18/1324/002 (500 IU); EU/1/18/1324/003 (1000 IU); EU/1/18/1324/004 (2000 IU); EU/1/18/1324/005 (3000 IU).

Date of last revision of SmPC: 22.11.2018.

In the Czech Republic Jivi is prescription only medicine. Jivi is not covered by the public health insurance. It is not yet available on the Czech market. You can find complete product information in the Summary of Product Characteristic (SmPC) or contact your local representative of the registration holder.

MA-JIV-CZ-0001-1
12/2018