▼**This medicinal product is subject to additional monitoring.** By registering to take part in this event you consent to notify Bayer of any Adverse Events (AEs) regarding Bayer product(s) and service(s) that come to your attention within 1 business day of becoming aware of the AE. This requirement applies for the duration of the event. You may inform a Bayer representative at the event or by calling 1800 008 757. This will be considered sufficient to fulfilling your Pharmacovigilance reporting requirements.

Jivi 250 / 500 / 1000 / 2000 / 3000 IU powder and solvent for solution for injection
(Refer to full SmPC before prescription.)
Composition: site specifically PEGylated recombinant human coagulation factor VIII, 250/500/1000/2000/3000 IU/vial (100/200/400/800/1200 IU/ml after reconstitution). *Excipients:* Powder: Sucrose, Histidine, Glycine, Sodium chloride, Calcium chloride dihydrate, Polysorbate 80, glacial acetic acid (for pH adjustment). Solvent: Water for injections. **Indication:** Treatment and prophylaxis of bleeding in previously treated patients ≥ 12 years of age with haemophilia A (congenital factor VIII deficiency). **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. The formation of neutralising antibodies (inhibitors) to FVIII is a known complication in the management of individuals with haemophilia A. 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. **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 papular), injection site reactions (incl. injection site pruritus/rash and vessel puncture site pruritus), pyrexia; *uncommon:* FVIII inhibition (previously treated patients), dysgeusia, flushing, pruritus.
On prescription only.
Marketing Authorisation Holder: Bayer AG, 51368 Leverkusen, Germany.
Date of revision of the underlying Prescribing Information: November 2018