FEIBA (Factor VIII Inhibitor Bypassing Activity) 50 U/ml powder and solvent for solution for infusion
PRESCRIBING INFORMATION for GREAT BRITAIN (ENGLAND, SCOTLAND, WALES)
Refer to the Summary of Product Characteristics (SmPC) before prescribing

Presentation: 1 vial of FEIBA 50 U/ml contains 500 U, 1000 U or 2500 U factor VIII inhibitor bypassing activity.

Indications: Treatment of spontaneous bleeding and cover of surgical interventions in haemophilia A patients with factor VIII inhibitors and in non-haemophiliacs with acquired factor VIII inhibitors. Prophylaxis in haemophilia A patients with high responding inhibitors and frequent joint bleeding.

Dosage and administration: Treatment should be initiated and supervised by a physician experienced in the management of haemophilia. Posology: The dosage and duration of the therapy is dependent upon the severity of the disorder, the location and extent of the bleeding and the patient's clinical condition. As a general guide a dose of 50 to 100 U of FEIBA per kg body weight is recommended, repeated every 6 – 12 hours depending on type of bleed and degree of response (for further information on dosage please refer to the SmPC). Dosage and frequency of administration should always be guided by the clinical efficacy in each individual case. FEIBA should be administered via the intravenous route at a maximum rate of 2 U/kg body weight per minute. A single dose of 100 U/kg body weight and a daily dose of 200 U/kg body weight should not be exceeded unless the severity of bleeding warrants and justifies the use of higher doses. Bleeding prophylaxis: For prevention of bleeding episodes during prophylaxis, dose 70 to 100 U/kg body weight every other day. Adjust dose based on the patient's clinical response. Paediatrics: The experience in children under 6 years of age is limited; the same dose regimen as in adults should be adapted to the child's clinical condition. Monitoring: In case of inadequate response to treatment with the product, it is recommended that a platelet count be performed because a sufficient number of functionally intact platelets are considered to be necessary for the efficacy of the product. Results of routine coagulation tests may not correlate with clinical improvement – no direct monitoring is possible. Global haemostatic tests such as thromboelastogram (TEG) or thrombin generation assay (TGA) may be useful tools to monitor and optimise the treatment. **Contraindications:** FEIBA must not be used in the following situations if therapeutic alternatives to FEIBA are available: Hypersensitivity to the active substance or to any of the excipients. Disseminated intravascular coagulation (DIC). Acute thrombosis or embolism (including myocardial infarction). **Warnings and precautions:** Traceability: Name and the batch number of the administered product should be clearly recorded. Thromboembolic events: Have occurred, including DIC, venous thrombosis, pulmonary embolism, myocardial infarction, and stroke. Some occurred with doses above 200 U/kg/day or in patients with other risk factors for thromboembolic events (including DIC, advanced atherosclerotic disease, crush injury or septicaemia). FEIBA should be used with particular caution in patients at risk of DIC, arterial or venous thrombosis. Thrombotic microangiopathy (TMA) has not been reported in FEIBA clinical studies. Cases of TMAs were reported in an emicizumab clinical trial where subjects received FEIBA as part of a treatment regimen for breakthrough bleeding. If treatment with FEIBA is considered required for patients receiving emicizumab, patients must be closely monitored. At the first signs or symptoms of thromboembolic events, the infusion should be stopped immediately, and appropriate diagnostic and therapeutic measures initiated. A single dose of 100 U/kg body weight and a daily dose of 200 U/kg body weight should not be exceeded. When used to stop bleeding, the product should be given only for as long as absolutely necessary to achieve the therapeutic goal. Allergic-type hypersensitivity reactions: FEIBA can precipitate allergic-type hypersensitivity reactions that have included, urticaria, angioedema, gastrointestinal manifestations, bronchospasm, and hypotension; these reactions can be severe and can be systemic (e.g. anaphylaxis with urticaria and angioedema, bronchospasm, and circulatory shock). At the first sign or symptom of an infusion/hypersensitivity reaction, FEIBA administration should be stopped and medical care initiated as appropriate. Measures to prevent transmission of infectious agents: Standard measures for safety of plasma products are employed but the risk of transmission of infective agents cannot be excluded. The measures taken may be of limited value against nonenveloped viruses such as parvovirus B19. Parvovirus B19 infection may be serious for pregnant women (foetal infection) and for individuals with immunodeficiency or increased erythropoiesis (e.g. haemolytic anaemia). Appropriate vaccination (against hepatitis A and B) should be considered for patients in regular/repeated receipt of plasma-derived products. Discordant response to bypassing agents: Due to patient-specific factors the response to a bypassing agent can vary, in case of insufficient response to one bypassing agent, use of another agent should be considered. Anamnestic responses: Patients with inhibitors may result in an initial "anamnestic" rise in the inhibitor levels. Continuous administration of FEIBA may decrease the inhibitors over time. Interference with laboratory tests: High doses of FEIBA may result in misleading interpretation of positive results in serological testing. Sodium content: FEIBA contains approximately 4 mg sodium (calculated) per ml. To be taken into consideration in patients on a low sodium diet. **Interactions:** No adequate and well-controlled studies of the combined or sequential use of FEIBA and recombinant factor VIIa (rFVIIa), antifibrinolytics or emicizumab have been conducted. The possibility of thromboembolic events should be considered when systemic antifibrinolytics are used. Therefore, antifibrinolytics and FEIBA should be administered at least 6 hours apart. In cases of concomitant rFVIIa use, a potential drug interaction may occur (potentially resulting in adverse events such as a thromboembolic event). Clinical experience from an emicizumab clinical trial suggests that a potential drug interaction may exist with emicizumab when FEIBA was used as part of a treatment regimen for breakthrough bleeding. **Fertility, pregnancy and lactation:** There are no adequate data from the use of FEIBA in pregnant or lactating women. **Undesirable effects:** Common (≥1/100 to <1/10): Hypersensitivity, headache, dizziness, hypotension, rash, and hepatitis B surface antibody positive. Other serious undesirable effects (unknown frequency): DIC,

anamnestic response, anaphylactic reaction, embolic stroke, thrombotic stroke, cardiac infarction, arterial thrombosis, hypertension, thrombosis, venous thrombosis, bronchospasm, dyspnoea, pulmonary embolism, angioedema, pyrexia, tachycardia. **Refer to the SmPC for details on full side effect profile and interactions**. **UK basic NHS price:** 50 U/ml powder/solvent: 500 U/10 ml – £390, 1000 U/20 ml – £780, 2500 U/50 ml – £1950. **Legal classification:** POM. **Marketing authorisation (MA) number:** PL 34078/0003.
Business responsible for sale: Takeda UK Ltd, 1 Kingdom Street, London, W2 6BD, United Kingdom.
PI approval code: pi-02306.
Date of preparation: January 2023.

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 Takeda at: AE.GBR-IRL@takeda.com

FEIBA (Factor VIII Inhibitor Bypassing Activity) 50 U/ml powder and solvent for solution for infusion
PRESCRIBING INFORMATION for NORTHERN IRELAND
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Presentation: 1 vial of FEIBA 50 U/ml contains 500 U, 1000 U or 2500 U factor VIII inhibitor bypassing activity.

Indications: Treatment of spontaneous bleeding and cover of surgical interventions in haemophilia A patients with factor VIII inhibitors and in non-haemophiliacs with acquired factor VIII inhibitors. Prophylaxis in haemophilia A patients with high responding inhibitors and frequent joint bleeding.

Dosage and administration: Treatment should be initiated and supervised by a physician experienced in the management of haemophilia. Posology: The dosage and duration of the therapy is dependent upon the severity of the disorder, the location and extent of the bleeding and the patient's clinical condition. As a general guide a dose of 50 to 100 U of FEIBA per kg body weight is recommended, repeated every 6 – 12 hours depending on type of bleed and degree of response (for further information on dosage please refer to the SmPC). Dosage and frequency of administration should always be guided by the clinical efficacy in each individual case. FEIBA should be administered via the intravenous route at a maximum rate of 2 U/kg body weight per minute. A single dose of 100 U/kg body weight and a daily dose of 200 U/kg body weight should not be exceeded unless the severity of bleeding warrants and justifies the use of higher doses. 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Global haemostatic tests such as thromboelastogram (TEG) or thrombin generation assay (TGA) may be useful tools to monitor and optimise the treatment. **Contraindications:** FEIBA must not be used in the following situations if therapeutic alternatives to FEIBA are available: Hypersensitivity to the active substance or to any of the excipients. Disseminated intravascular coagulation (DIC). Acute thrombosis or embolism (including myocardial infarction). **Warnings and precautions:** Traceability: Name and the batch number of the administered product should be clearly recorded. Thromboembolic events: Have occurred, including DIC, venous thrombosis, pulmonary embolism, myocardial infarction, and stroke. Some occurred with doses above 200 U/kg/day or in patients with other risk factors for thromboembolic events (including DIC, advanced atherosclerotic disease, crush injury or septicaemia). 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thrombotic stroke, cardiac infarction, arterial thrombosis, hypertension, thrombosis, venous thrombosis, bronchospasm, dyspnoea, pulmonary embolism, angioedema, pyrexia, tachycardia. **Refer to the SmPC for details on full side effect profile and interactions**. **UK basic NHS price:** 50 U/ml powder/solvent: 500 U/10 ml – £390, 1000 U/20 ml – £780, 2500 U/50 ml – £1950. **Legal classification:** POM. **Marketing authorisation (MA) number:** PL 34078/0003.
Business responsible for sale: Takeda UK Ltd, 1 Kingdom Street, London, W2 6BD, United Kingdom.
PI approval code: pi-02307.
Date of preparation: January 2023.

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