Summary of Product Characteristics

This Summary of Product Characteristics is intended for international use only. Please always consult your full country-specific summary of product characteristics/prescribing information as licenses and licensing conditions may vary from country to country.

1. NAME OF THE MEDICINAL PRODUCT
FEIBA 500 U powder and solvent for solution for injection.
FEIBA 1000 U powder and solvent for solution for injection.
FEIBA 2500 U powder and solvent for solution for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Active substance: Factor VIII Inhibitor Bypassing Activity
As the active ingredient, FEIBA 500 U* contains 500 U factor VIII bypassing activity in 200–600 mg human plasma protein.
As the active ingredient, FEIBA 1000 U* contains 1000 U factor VIII bypassing activity in 400–1200 mg human plasma protein.
As the active ingredient, FEIBA 2500 U* contains 2500 U factor VIII bypassing activity in 1000–3000 mg human plasma protein.
FEIBA also contains the factors II, IX and X, mainly in non-activated form, as well as activated factor VII. Factor VIII coagulation antigen (F VIII C:Ag) is present at a concentration of up to 0.1 U/1 U FEIBA. The factors of the kallikrein-kinin system are present in trace amounts only, if at all.

*1 unit of FEIBA shortens the activated partial thromboplastin time (aPTT) of a factor VIII inhibitor plasma by 50% of the buffer value (blank value).
For a complete listing of the excipients, see Section 6.1.

3. PHARMACEUTICAL FORM
Powder and solvent for solution for injection.
White, off-white or pale green freeze-dried powder or friable solid. The pH value of the reconstituted solution is between 6.8 and 7.6.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications

- Therapy and prophylaxis of bleeding in haemophilia A patients with inhibitor to factor VIII
- Therapy and prophylaxis of bleeding in haemophilia B patients with inhibitor to factor IX
- Therapy and prophylaxis of bleeding in non-haemophiliacs with acquired inhibitors to factors VIII, IX and XI

In combination with factor VIII concentrate, FEIBA was also used for long-term therapy to achieve complete and permanent elimination of the factor VIII inhibitor.

In three cases, FEIBA was also used in patients with an inhibitor to von Willebrand factor.

4.2 Posology and method of administration
Treatment should be initiated and supervised by a physician experienced in the management of haemophilia.

4.2.1 Posology
Dosage and duration of treatment depend on the severity of the haemostatic disorder, the localisation and the extent of the bleeding and the clinical condition of the patient.
Dosage and frequency of administration should always be guided by the clinical efficacy in each individual case.
As a general guideline, a dose of 50–100 U FEIBA per kg body weight is recommended. However a single dose of 100 U/kg body weight and a maximum daily dose of 200 U/kg body weight must not be exceeded unless the severity of bleeding warrants and justifies the use of higher doses. See Section 4.4.

Paediatric use (children)
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.

1) Spontaneous Haemorrhage
Joint, muscle and soft tissue haemorrhage
A dose of 50–75 U/kg body weight at 12-hour intervals is recommended for minor to moderate bleeds. The treatment is to be continued until clear signs of clinical improvement such as reduction of pain, decrease of swelling or increase of joint mobility, occur.
For major muscle and soft tissue haemorrhage, such as retroperitoneal haemorrhages, a dose of 100 U/kg body weight at 12-hour intervals is recommended.

Mucous membrane haemorrhage
A dose of 50 U/kg body weight every 6 hours under careful monitoring of the patient (visual control of bleeding, repeated determination of haematocrit) is recommended. If bleeding does not stop, the dose may be increased to 100 U/kg body weight, however not exceeding a daily dose of 200 U/kg body weight.
Other severe haemorrhages
In severe haemorrhage, such as CNS bleeding, a dose of 100 U/kg body weight at 12-hour intervals is recommended. In individual cases, FEIBA may be administered at 6-hour intervals, until clear improvement of the clinical condition is achieved. (The maximum daily dose of 200 U/kg body weight must not be exceeded!).

2) Surgery
Taking into consideration the maximum daily dose, 50–100 U/kg body weight at 6-hour intervals should be administered.

3) Prophylaxis
• Prophylaxis of bleeding in patients with high inhibitor titre and with frequent bleedings in whom ITI (immune tolerance induction) has failed or is not considered: A dose of 70–100 U/kg body weight every other day is recommended. This dose may be increased up to 100 U/kg body weight every day if the patient continues to bleed or may gradually be decreased.
• Prophylaxis of bleeding in patients with high inhibitor titre undergoing ITI (immune tolerance induction): FEIBA may be administered concomitantly with factor VIII concentrates, in a dosage range of 50–100 U/kg body weight, twice per day until the factor VIII inhibitor has been reduced to < 2 B.U.*

*1 Bethesda Unit is defined as the amount of antibody that will inhibit 50% of the FVIII activity of fresh average human plasma after incubation for 2 hours at 37°C.

4.2.2 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 is considered to be necessary for the efficacy of the product.

Due to the complex mechanism of action, no direct monitoring of active ingredients is available. Coagulation tests such as the whole blood clotting time (WBCT), the thromboelastogram (TEG, r-value) and the aPTT usually show only a slight shortening and do not have to correlate with the clinical efficacy. Therefore these tests have only a low significance in monitoring therapy with FEIBA. See Section 4.4.

4.2.3 Method of administration
Reconstitute the product as described in Section 6.6 and slowly inject or infuse it via the intravenous route. An injection speed of 2 U/kg body weight per minute must not be exceeded.

4.3 Contraindications
FEIBA must not be used in the following situations if therapeutic alternatives to FEIBA are available:
• Hypersensitivity to the product or any of the components
• Disseminated intravascular coagulation (DIC)
• Acute thrombosis or embolism (including myocardial infarction)

See Section 4.4.

4.4 Special warnings and special precautions for use

WARNINGS
Risk of Thrombotic and Thromboembolic Events
Thrombotic and thromboembolic events, including DIC, venous thrombosis, pulmonary embolism, myocardial infarction and stroke, have occurred in the course of treatment with FEIBA.

The risk of thrombotic and thromboembolic events may be increased with high doses of FEIBA. Some of these events occurred with doses above 200 U/kg/day or in patients with other risk factors for thromboembolic events. The possible presence of such risk factors should always be considered in patients with congenital and acquired haemophilia.

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. Patients receiving more than 100 U/kg body weight must be monitored for the development of DIC and/or acute coronary ischemia. When used to stop bleeding, the product should be given only for as long as absolutely necessary to achieve the therapeutic goal.

In the following situations, FEIBA is to be applied only if no reaction to treatment with suitable blood coagulation factor concentrates can be expected, e.g. in case of a high inhibitor titre and a life-threatening haemorrhage or risk of bleeding (e.g. posttraumatic or postoperative):
• Disseminated intravascular coagulation (DIC):
  – Liver damage: due to the delayed clearance of activated coagulation factors, patients with impaired liver function are at increased risk of developing DIC
• Coronary heart disease, acute thrombosis and/or embolism

Allergic-Type Hypersensitivity Reactions
As with any intravenously administered plasma products, allergic-type hypersensitivity reactions may occur. Patients should be informed of the early signs of hypersensitivity reactions including hives, generalised urticaria, tightness of the chest, wheezing, drop in blood pressure and
anaphylactic shock. If these symptoms occur, patients should be advised to discontinue the treatment and to contact their physician immediately. Shock is treated according to the rules of modern shock therapy.

When considering re-exposure to FEIBA in patients with suspected hypersensitivity to the product or any of its components, the expected benefit and the risk of re-exposure must be carefully weighed, taking into account the known or suspected type of the patient’s hypersensitivity (allergic or non-allergic), including potential remedial and/or preventative therapy or alternative therapeutic agents.

**Therapy monitoring**

Individual doses of 100 U/kg body weight and daily doses of 200 U/kg body weight must not be exceeded. Patients who receive an individual dose of 100 U/kg body weight are to be monitored carefully, particularly with regard to the development of a DIC or the occurrence of symptoms of acute coronary ischaemia. High doses of FEIBA should be administered only as long as strictly necessary to stop a haemorrhage.

If clinically significant changes in blood pressure or pulse rate, respiratory distress, coughing or chest pain occur, the infusion is to be discontinued immediately and appropriate diagnostic and therapeutic measures are to be initiated. Laboratory parameters indicative of DIC are decreased fibrinogen values, decreased platelet count and/or the presence of fibrin/fibrinogen degradation products (FDP).

**Acquired haemophilia**

Patients with inhibitor haemophilia or with acquired inhibitors to coagulation factors, who are treated with FEIBA, may have increased bleeding tendency as well as increased risk of thrombosis at the same time.

**Laboratory tests and clinical efficacy**

*In vitro* tests, such as aPTT, whole blood clotting time (WBCT) and thromboelastograms (TEG) as proof of efficacy do not have to correlate with the clinical picture. Therefore, attempts to normalise these values by increasing the dose of FEIBA cannot be successful, and are even to be strongly rejected because of the possible risk of triggering a DIC through overdosing.

**Significance of the thrombocyte count**

If the response to treatment with FEIBA is inadequate, conducting a thrombocyte count is recommended since a sufficient number of functionally intact thrombocytes is necessary for the efficacy of FEIBA.

**Measures to Prevent Transmission of Infectious Agents**

When medicines are made from human blood or plasma, certain measures are put in place to prevent infections being passed on to patients. These include careful selection of blood and plasma donors to make sure those at risk of carrying infections are excluded, and the testing of each donation and pools of plasma for signs of virus/infections. Manufacturers of these products also include steps in the processing of the blood or plasma that can inactivate or remove viruses. Despite these measures, when medicines prepared from human blood or plasma are administered, the possibility of passing on infection cannot be totally excluded. This also applies to any unknown or emerging viruses or other types of infections.

These measures taken are considered effective for enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV), and for the non-enveloped virus hepatitis A virus (HAV) and Parvovirus B19.

When a pharmaceutical prepared from human plasma is administered regularly/repeatedly, appropriate vaccination (hepatitis A and B) is recommended.

In the interest of patients, it is strongly recommended that name and batch number of the product be recorded every time FEIBA is administered in order to be able to link patient and product batch.

**PRECAUTIONS**

**Discordant Response to Bypassing Agents**

Due to patient-specific factors the response to a bypassing agent can vary, and in a given bleeding situation patients experiencing insufficient response to one agent may respond to another agent. In case of insufficient response to one bypassing agent, use of another agent should be considered.

**Anamnestic Responses**

Administration of FEIBA to patients with inhibitors may result in an initial anamnestic rise in inhibitor levels. Upon continued administration of FEIBA, inhibitors may decrease over time. Clinical and published data suggest that the efficacy of FEIBA is not reduced.

**Hepatitis B Surface Antibodies and Test Interpretation**

After administration of high doses of FEIBA, the transitory rise of passively transferred Hepatitis B surface antibodies may result in misleading interpretation of positive results in serological testing.

**Prophylactic Use**

Only limited clinical data is available on the application of FEIBA for the prophylaxis of bleeding in hemophilia patients.

**Excipient Related Considerations**

Pack sizes 500 U + 1000 U contain approximately 80 mg sodium (calculated) per vial. Pack size 2500 U contains approximately 200 mg sodium (calculated) per vial. This is to be taken into consideration in patients on a low sodium diet.
4.5 Interactions with other medicinal products and other forms of interaction
The possibility of thrombotic events should be considered when systemic antifibrinolytics such as tranexamic acid and aminocaproic acid are used during treatment with FEIBA. Therefore, antifibrinolytics should not be used for approximately 6 to 12 hours after the administration of FEIBA.

4.6 Fertility, pregnancy and lactation
There are no adequate data from the use of FEIBA in pregnant or lactating women. Physicians should balance the potential risks and only prescribe FEIBA if clearly needed, taking into consideration that pregnancy and the postpartum period confer an increased risk of thromboembolic events and several complications of pregnancy that are associated with an increased risk of DIC.

No animal reproduction studies have been conducted with FEIBA, and the effects of FEIBA on fertility have not been established in controlled clinical trials.

4.7 Effects on the ability to drive and use machines
No effects on the ability to drive and use machines have been observed.

4.8 Undesirable effects
The following adverse reactions have been reported within the framework of either post-marketing surveillance or clinical trials. The frequency cannot be estimated due to the nature of the data and therefore is categorized as unknown.

<table>
<thead>
<tr>
<th>System organ classes according to MedDRA</th>
<th>Undesirable effects</th>
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</thead>
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<tr>
<td>Blood and lymphatic system disorders</td>
<td>Disseminated intravascular coagulation (DIC)</td>
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<tr>
<td></td>
<td>Increase of inhibitor titre (anamnestic response)</td>
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<tr>
<td>Immune system disorders</td>
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<td></td>
<td>Urticaria</td>
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<td></td>
<td>Anaphylactic reaction</td>
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<tr>
<td>Nervous system disorders</td>
<td>Paresthesia</td>
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<td></td>
<td>Hypoaesthesia</td>
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<td></td>
<td>Thrombotic stroke</td>
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<td>Embolic stroke</td>
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<td>Headache</td>
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<td>Somnolence</td>
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<td>Dizziness</td>
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<td>Dysgeusia</td>
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<td>Cardiac disorders</td>
<td>Cardiac infarction</td>
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<td>Tachycardia</td>
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<td>Vascular disorders</td>
<td>Embolism (thromboembolic complications)</td>
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<td>Hypotension</td>
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<td>Hypertension</td>
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<td>Respiratory, thoracic, and mediastinal disorders</td>
<td>Pulmonary embolism</td>
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<td></td>
<td>Bronchospasm</td>
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<td>Wheezing</td>
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<td>Cough</td>
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<td></td>
<td>Dyspnea</td>
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<td>Gastrointestinal disorders</td>
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<td>Skin and subcutaneous tissue disorders</td>
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<td></td>
<td>Angioedema</td>
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<td>Urticaria</td>
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<td>Pruritus</td>
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<td>Rash</td>
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<tr>
<td>System organ classes according to MedDRA</td>
<td>Undesirable effects</td>
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<tr>
<td>General disorders and administration site conditions (disorders during injection)</td>
<td>Injection site pain</td>
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<tr>
<td>Malaise</td>
<td>Feeling hot</td>
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<td>Feeling hot</td>
<td>Chills</td>
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<tr>
<td>Pyrexia</td>
<td>Chest pain</td>
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<td>Chest discomfort</td>
<td>Chest discomfort</td>
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<tr>
<td>Investigations</td>
<td>Blood pressure decreased</td>
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</tbody>
</table>

*Increase of inhibitor titre (anamnestic response) [not a MedDRA PT] is the rise of previously existing inhibitor titres occurring after the administration of FEIBA. See Section 4.4.

Rapid intravenous injection or infusion may cause a stabbing pain and numbness in the face and extremities as well as a drop in blood pressure.

Thromboembolic events might occur after the administration of doses above the maximum daily dose and/or prolonged application. See Section 4.4.

For safety with respect to transmissible agents, see Section 4.4.

4.9 Overdose

The risk of thrombotic and thromboembolic events (including DIC, myocardial infarction, venous thrombosis and pulmonary embolism) may be increased with high doses of FEIBA. Some of the reported events occurred with doses above 200 U/kg or with patients with other risk factors for thromboembolic events. If signs or symptoms of thrombotic and thromboembolic events are observed, the infusion should be stopped immediately and appropriate diagnostic and therapeutic measures initiated. See Section 4.4.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: activated prothrombin complex against factor VIII antibodies, ATC code: B02BD03.

Although FEIBA was developed in the early 1970s and its factor VIII inhibitor bypassing activity has been demonstrated both *in vitro* and *in vivo*, its active principle is still the subject of scientific debate. However, recent scientific work indicates a role of specific components of the activated prothrombin complex, zymogen prothrombin (F II) and activated Factor X (FXa), in the FEIBA mode of action.

5.2 Pharmacokinetic properties

Since FEIBA is composed of different coagulation factors with varying half-lives for the single components, it is not possible to make any definite statement with regard to the pharmacokinetic properties of FEIBA.

5.3 Preclinical safety data

Based on acute toxicity studies in factor VIII knockout mice and in normal mice, and in rats with doses higher than the maximum daily dose in humans (> 200 U /kg body weight), it can be concluded that the side effects in connection with FEIBA are mainly the result of hypercoagulation due to the pharmacological properties.

Toxicity studies with repeated administration in animal experiments are practically unfeasible as interference occurs through the development of antibodies to heterologous proteins.

Since human blood coagulation factors are not seen as carcinogenic or mutagenic, experimental animal studies, especially in heterologous species, were not considered necessary.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Powder: Sodium chloride
Sodium citrate
Solvent: Sterilised water for injections

6.2 Incompatibilities

In order not to impair the efficacy and compatibility of the preparation, FEIBA, like all coagulation factor concentrates, must not be mixed with other medicinal products prior to administration. It is advisable to rinse a common venous access with a suitable solution, e.g. with isotonic saline solution, before and after the administration of FEIBA.

Coagulation factors derived from human plasma may be adsorbed by the inner surfaces of certain types of injection/infusion devices. If this were to occur, it could result in failure of therapy. Therefore, only approved plastic infusion devices may be used with FEIBA.

6.3 Shelf life

Two years.

The chemical and physical stability of the reconstituted solution has been proven for 3 hours at 20°C to 25°C.
From a microbiological viewpoint, FEIBA should be used immediately after reconstitution. If the ready-for-use solution is not administered promptly, the user is responsible for storage conditions and time.

The ready-to-use solution must not be refrigerated.

6.4 Special precautions for storage
Do not store above 25°C. Do not freeze.
Store in the original package in order to protect the content from light.

6.5 Nature and contents of container
FEIBA powder and solvent are supplied in vials made of surface-treated, colorless glass (powder vial: hydrolytic Type II; solvent vial: hydrolytic Type I). The vials are closed with butyl rubber stoppers and protective caps.

The FEIBA 500 U package contains either:
1 vial with FEIBA 500 U
1 vial with 20 mL sterilised water for injection
1 disposable syringe
1 disposable needle
1 filter needle
1 transfer needle
1 aeration needle
1 butterfly needle with clamp
or
1 vial with FEIBA 500 U
1 vial with 20 mL sterilised water for injection
1 BAXJECT II Hi-Flow
1 disposable syringe
1 disposable needle
1 butterfly needle with clamp

The FEIBA 1000 U package contains either:
1 vial with FEIBA 1000 U
1 vial with 20 mL sterilised water for injection
1 disposable syringe
1 disposable needle
1 filter needle
1 transfer needle
1 aeration needle
1 butterfly needle with clamp
or
1 vial with FEIBA 1000 U
1 vial with 20 mL sterilised water for injection
1 BAXJECT II Hi-Flow—needleless transfer device intended for transferring and mixing drugs contained in two vials into a syringe
1 disposable syringe
1 disposable needle
1 butterfly needle with clamp

The FEIBA 2500 U package contains:
1 vial with FEIBA 2500 U
1 vial with 50 mL sterilised water for injection
1 BAXJECT II Hi-Flow—needleless transfer device intended for transferring and mixing drugs contained in two vials into a syringe
1 disposable syringe
1 disposable needle
1 butterfly needle with clamp

6.6 Special precautions for disposal and other handling advice
To prepare the FEIBA solution, use only the sterilised water for injections and the reconstitution device provided in the pack. Use aseptic technique throughout entire procedure.

FEIBA is to be reconstituted only immediately before administration. The solution should then be used straight away (the solution does not contain preservatives).

Swirl gently until all material is dissolved. Ensure that FEIBA is completely dissolved; otherwise, less FEIBA units will pass through the device filter.
After reconstitution, the solution should be inspected for particulate matter and discoloration prior to administration. Do not use solutions which are cloudy or have deposits.

Do not use if the needleless transfer device or the transfer needle, its sterile barrier system or its packaging is damaged or shows any sign of deterioration.

Any unused medicinal product or waste material is to be disposed of in accordance with national requirements.

Reconstitution of the powder for solution for injection with the BAXJECT II Hi-Flow:

1. Warm solvent (sterilised water for injection) vial to room temperature (15 °C – 25 °C), for example by using a water bath for several minutes (max. 37°C) if necessary.
2. Remove the protective caps from the FEIBA vial and solvent vial and cleanse the rubber stoppers of both. Place the vials on a flat surface.
3. Open the BAXJECT II Hi-Flow device package by peeling away the paper lid without touching the inside (Fig a). Do not remove the device from the package.
4. Turn the package over and insert the clear plastic spike through the solvent stopper (Fig. b). Grip the package at its edge and pull the package off BAXJECT II Hi-Flow (Fig. c). Do not remove the blue cap from BAXJECT II Hi-Flow device.
5. With BAXJECT II Hi-Flow attached to the solvent vial, invert the system so that the solvent vial is on top of the device. Insert the purple plastic spike through the FEIBA vial stopper. The vacuum will draw the solvent into the FEIBA vial (Fig. d).
6. Swirl, but do not shake, the entire system gently until all material is dissolved. Ensure that FEIBA is completely dissolved, otherwise active material will not pass through the device filter.

Instructions for injection/infusion:

1. Remove the blue cap from BAXJECT II Hi-Flow. Tightly connect the syringe to BAXJECT II Hi-Flow. DO NOT DRAW AIR INTO THE SYRINGE (Fig. e). In order to ensure tight connection between syringe and BAXJECT II Hi-Flow, the use of a luer lock syringe is highly recommended (turn syringe in clockwise direction until stop position when mounting).
2. Invert the system so that the dissolved product is on top. Draw the FEIBA solution into the syringe by pulling the plunger back SLOWLY and ensure that the tight connection between BAXJECT II Hi-Flow and the syringe is maintained throughout the whole pulling process (Fig. f).
3. Disconnect the syringe.
4. If foaming of the product in the syringe occurs, wait until the foam is collapsed. Slowly administer the solution intravenously with the enclosed infusion set (or a disposable needle).

Do not exceed an injection speed of 2 U FEIBA/kg body weight per minute.

Reconstitution of the powder for solution for injection with transfer needle:

1. Warm the unopened solvent (sterilised water for injections) vial to room temperature, e.g. using a sterile water bath for warming within several minutes (max. +37°C) if necessary.
2. Remove protective caps from the concentrate vial and solvent vial (Fig. A) and clean the rubber stoppers of both.
3. Remove protective covering from one end of the supplied transfer needle by twisting and pulling (Fig. B). Insert the exposed needle through the rubber stopper of the solvent vial (Fig. C).
4. Remove protective covering from the other end of the transfer needle taking care not to touch the exposed end.
5. Invert the solvent vial over the concentrate vial, and insert the free end of the transfer needle through the rubber stopper of the concentrate vial (Fig. D). The solvent will be drawn into the concentrate vial by vacuum.
6. Disconnect the two vials by removing the needle from the concentrate vial (Fig. E). Gently agitate or rotate the concentrate vial to accelerate dissolution.
7. Upon complete reconstitution of the concentrate, insert the enclosed aeration needle provided (Fig. F) and any foam will collapse. Remove aeration needle.

**Instructions for injection/infusion:**

Use aseptic technique throughout entire procedure.

1. Remove protective covering from the supplied filter needle by twisting and pulling and fit the needle onto a sterile disposable syringe. Draw the solution into the syringe (Fig. G).
2. Disconnect the filter needle from the syringe and slowly inject the solution intravenously with the enclosed winged set for injection (or the enclosed disposable needle).

![Images of procedure steps](Fig. A Fig. B Fig. C Fig. D Fig. E Fig. F Fig. G)

Do not exceed an injection speed of 2 U FEIBA/kg body weight per minute.

If devices other than those supplied with FEIBA are used, ensure use of an adequate filter with at least 149 µm pore size.

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7. MARKETING AUTHORISATION HOLDER
   <country specific>

8. MARKETING AUTHORISATION NUMBER
   <country specific>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
   <country specific>

10. DATE OF REVISION OF THE TEXT
    July 2013 <country specific>

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