Package leaflet: Information for the user

FEIBA 50 U/ml
Powder and Solvent for Solution for Infusion

Active substance: Factor VIII Inhibitor Bypassing Activity

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Throughout this leaflet Feiba 50 U/ml Powder and Solvent for Solution for Infusion will be called FEIBA.

In this leaflet:

1. What FEIBA is and what it is used for

FEIBA is a concentrate of blood factors normally present in your blood that help it to clot. It is used to help clotting in patients who have developed inhibitors (antibodies) to factor VIII (factor 8). Haemophilia A patients have lower Factor VIII levels than normal. So, if anything stops the factor from working your blood will not clot properly. FEIBA makes sure that your blood clots properly.

FEIBA is used:
- To treat spontaneous bleeding episodes in haemophilia A patients with inhibitors (haemophilia is when your blood does not clot properly)
- In haemophilia A patients with inhibitors if they need surgery
- In haemophilia A patients with inhibitors to prevent frequent bleeding
- To treat non-haemophiliacs who have developed antibodies in their blood that prevent factor VIII from working

2. What you need to know before you use FEIBA

Do not use FEIBA:
- if you are allergic to Factor VIII Inhibitor Bypassing Activity or any of the other ingredients of this medicine (listed in section 6).
- if you have a condition that affects blood clotting called ‘Disseminated Intravascular Coagulation’ or DIC. This can cause blood clots, bleeding and sudden bruising. DIC occurs after a serious disease, injury, or after a major operation. It will be found by your doctor using laboratory tests.

Do not use FEIBA if any of the above apply to you. If you are not sure talk to your doctor, pharmacist or nurse before using FEIBA.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using FEIBA:
- if you have liver problems
- if you have suffered a heart attack
- if you have a blood clot (thrombosis or embolism)
- if your immune system isn't working properly
- if you are on a low sodium diet.

Some people have experienced the following side effects while using FEIBA. Your risk of getting these side effects is increased if you use high doses of FEIBA:
- Disseminated intravascular coagulation (DIC) (shown in tests)
- Blood clots in the veins or lungs
- Heart attack
- Stroke.

You may experience an allergic reaction when using FEIBA, these reactions include a nettle-rash (urticaria), swelling of the face, tongue or lips, wheezing or difficulty in breathing or a drop in blood pressure. Other infusion reactions may include chills, fever and high blood pressure.

If you get any of these side-effects, stop the infusion immediately and get urgent medical advice.

Your doctor may re-use FEIBA in patients who are, or who may be allergic (hypersensitive) to the product or any of its ingredients. They will only do this after careful consideration of the expected benefits and the risks of using the product.

A few patients treated with emicizumab and then given bypassing agents like FEIBA, experienced thrombotic microangiopathy (TMA). If you experience any of these symptoms: fatigue, dizziness, bruising, confusion, seizures, decreased urine output, or swollen legs contact your haemophilia doctor or Haemophilia Treatment Centre, or if those are unavailable, seek urgent medical attention as TMA is potentially life threatening. If treatment with FEIBA is required for patients receiving emicizumab, you must be closely monitored by your haemophilia doctor.

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. FEIBA is a plasma derived product and could contain substances that react when infused in patients, causing the presence of isohaemagglutinins (antibodies that cause the adhesion of red blood cells from another person). This process can lead to misleading results in blood tests.

Tell your doctor, pharmacist or nurse straight away if you notice any of these side effects.

FEIBA is made from human blood or plasma. This means blood from donors is used to make FEIBA. The following measures are used to make sure this does not transmit infections:
- Donors are carefully screened and selected
- When FEIBA is made steps are taken to remove and destroy the AIDS HIV virus and certain others that cause liver problems (such as hepatitis A, hepatitis B and hepatitis C viruses). These steps may be of limited value against a virus called parvovirus B19

As with any medicine made from human blood or plasma, the risk of transmission of infectious diseases cannot be totally ruled out.

Your doctor may recommend that you have vaccinations against hepatitis A and B if you regularly need products that are made using blood or blood components.

Other medicines and FEIBA
Tell your doctor, pharmacist or nurse if you are taking, have recently taken, or might take any other medicines, including medicines you have bought yourself.

Patients who are at risk of bleeding are sometimes given drugs to help make blood clots more stable and last longer – these are known as anti-fibrinolytics. No adequate and well-controlled studies of the combined or sequential use of FEIBA and anti-fibrinolytics, recombinant Factor VIIa or emicizumab have been conducted. These drugs may affect the way FEIBA works. Examples of these are epsilon-aminocaproic acid, or tranexamic acid. If your doctor tells you that you need to take these drugs as well as FEIBA, a gap of at least six hours should be left between them. The possibility of thromboembolic events should be considered when systemic anti-fibrinolytics are used during treatment with FEIBA. In cases of concomitant rFVIIa use a potential drug interaction cannot be excluded according to available in vitro data and clinical observations, potentially resulting in a thromboembolic event.
Tell your doctor if you are to be treated with FEIBA after you have received emicizumab (a medicine used for treating patients with haemophilia A who have developed factor VIII inhibitors). Your doctor will need to monitor you closely.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy
• FEIBA will only be used if no alternative treatment is available, because there is an increased risk of your blood clotting during pregnancy.
• You will be monitored very carefully by your doctor if you do need to have FEIBA during pregnancy.

Breast-feeding
Do not breast-feed while being treated with FEIBA.

Driving and using machines
No effects of FEIBA on the ability to drive and use machines have been observed.

Tests you may have with FEIBA
You will have your blood tested regularly to see how your treatment is working. If FEIBA doesn't seem to be working as well as expected, your doctor may carry out a test on your blood to count your platelets. Platelets help your blood to clot and the number affects how well FEIBA works.

FEIBA contains Sodium
500 U
This medicine contains 40 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 2% of the recommended maximum daily dietary intake of sodium for an adult.

1000 U
This medicine contains 80 mg sodium (main component of cooking/table salt) in each vial. This

is equivalent to 4% of the recommended maximum daily dietary intake of sodium for an adult.

2500 U
This medicine contains 200 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 10% of the recommended maximum daily dietary intake of sodium for an adult.

It is strongly recommended that every time you receive a dose of FEIBA the name and batch number of the product FEIBA are recorded in order to maintain a record of the batches used.

3. How to use FEIBA

Reconstitute the freeze-dried FEIBA powder with the enclosed solvent and administer the solution intravenously.
Always use FEIBA exactly as your doctor has instructed you. Please ask your doctor or pharmacist, if you are not entirely sure.
Taking into consideration the severity of the blood coagulation disorder, the location and extent of the haemorrhage, and your general condition and response to the preparation, the doctor has determined the dose and dosage intervals required for you personally. Do not change the dosage established by your doctor and do not discontinue the application of the preparation independently.
Please talk to your doctor or pharmacist if you have the impression that the effect of FEIBA is too strong or too weak.

The usual dose
- Your doctor will decide how much you will need, how often and at what intervals you need to have it. The solution should be given as an injection into your vein.
- As a guide, 70 to 100 units (U) per kg (kilogram) of body weight is recommended.
- The maximum single dose should not be more than 100 units per kg.
- The maximum dose in a day should not be more than 200 units per kg.

How to dissolve and inject FEIBA
- **Aseptic conditions (meaning clean and germ free) are required during preparation of the FEIBA solution and administration**
- FEIBA is to be reconstituted only immediately before administration. The solution should then be used immediately (the preparation does not contain preservatives).
- The BAXJECT II Hi-Flow is used to mix the powder with the Water for Injections. The BAXJECT II Hi-Flow will be referred to as ‘the device’ for the rest of the leaflet.
- Warm the product to room or body temperature prior to administration if necessary.
- Swirl gently until all material is dissolved. Ensure that FEIBA is completely dissolved; otherwise, less FEIBA Units will pass through the device filter.
- When you have mixed the powder with water (Water for Injections), use it immediately.
- Do not reuse opened containers.
- Use only the provided solvent (Water for Injections) and devices for reconstitution.
- If devices other than those supplied with FEIBA are used, ensure use of an adequate filter.

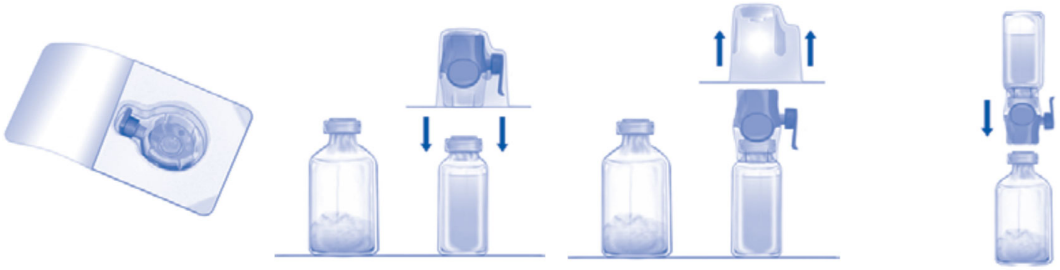
In order to ensure a tight connection between the syringe and BAXJECT II Hi-Flow, the use of a luer lock syringe is highly recommended (turn the syringe in a clockwise direction until the stop position when mounting).

- Any unused solution must be disposed of appropriately.
- This medicine must not be mixed with other medicines or solvents.
- Inject FEIBA solution in the way that you have been trained.

Dissolving the dried substance
When you have mixed the powder with solvent vial (Water for Injections) use it immediately.
Please see the diagrams below.

1. Warm the powder and solvent vials to room temperature (15°C – 25°C) if necessary.
2. Remove the protective caps from the powder and solvent vials and cleanse the rubber stoppers of both with alcohol wipes. Place the vials on a flat surface.
3. Open the device package by peeling away the paper lid without touching the inside (Fig. i). **Do not remove the device from the package.**
4. Do not use if the device, its sterile barrier system or its packaging has been previously opened, damaged or shows any sign of deterioration. Turn the package over and insert the clear plastic spike through the solvent vial stopper (Fig. ii). Grip the package at its edge and pull the package off the device (Fig. iii). Do not remove the blue cap from the device.
5. With the device attached to the solvent vial, invert the system so that the solvent vial is on top of the device. Insert the purple plastic spike of the device through the powder vial stopper. The vacuum will draw the solvent into the powder vial (Fig. iv)
6. Swirl, but do not shake, the entire system gently until all material is dissolved. Ensure that the powder is completely dissolved, otherwise active material will not pass through the device filter.

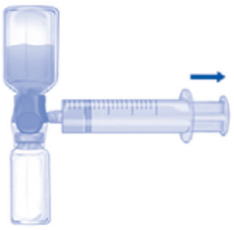
Fig. i Fig. ii Fig. iii Fig. iv



Do not use solutions that are cloudy or contain bits (deposits).

Injecting the dissolved product
In order to ensure a tight connection between the syringe and BAXJECT II Hi-Flow, the use of a luer lock syringe is highly recommended.
1. Remove the blue cap from the device. Take the syringe and connect it to the device (DO NOT DRAW AIR INTO THE SYRINGE) (Fig. v).
2. Invert the system (with product vial on top). Draw the FEIBA solution into the syringe by pulling the plunger back slowly (Fig. vi).
3. Disconnect the syringe.
4. If foaming of the product in the syringe occurs, wait until the foam has collapsed.
Slowly administer the solution intravenously with a winged set for injection (or a disposable needle).

Fig. v Fig. vi



Do not exceed an injection/infusion rate of 2 units FEIBA per kg of body weight per minute.

If FEIBA is given by infusion, a disposable infusion set with an adequate filter must be used.

If you are not sure about how to prepare or give the injection or if you have any other questions about your treatment, ask your doctor or nurse.

If you have more FEIBA than you should
If you think you have had too much FEIBA, stop the treatment quickly and speak to your doctor or nurse immediately. Sometimes if you have too much you may get the signs of 'Disseminated Intravascular Coagulation' or DIC. See above in section 2 'Do not take FEIBA if' for more information.

4. Possible side effects
Like all medicines, FEIBA can cause side effects, although not everybody gets them.

Tell your doctor, pharmacist or nurse straight away if you notice any of the following side effects. Sometimes they can be serious.

The following frequencies are used to evaluate side effects:

Very common:	may affect more than 1 in 10 people
Common:	may affect up to 1 in 10 people
Uncommon:	may affect up to 1 in 100 people
Rare:	may affect up to 1 in 1,000 people
Very rare:	may affect up to 1 in 10,000 people
Not known:	frequency cannot be estimated from the available data

In clinical trials the following side effects were reported as common:
Hypersensitivity
Headache
Dizziness
Hypotension
Rash
Hepatitis B surface antibody positive.

The following side effects have been reported during post marketing surveillance. The frequency cannot be estimated (not known) on the basis of the available data.
- **Blood and the lymphatic system:**
- Increase of inhibitor titre – shown in tests
- Disseminated intravascular coagulation (DIC) – shown in tests.

- **Immune system:**
- Anaphylactic reaction (severe allergy).
- **Nervous system:**
- Stroke
- Feeling sleepy
- Changes in the way things taste
- Feeling of numbness in the arms or legs
- Abnormal or reduced sensation.
- **Heart and circulation:**
- Flushing
- Palpitation of the heart
- High blood pressure
- Blood clots – signs may include pain in the legs or other places or difficulty breathing
- Heart attack – the risk is higher if you use high doses, or are treated for a long time when other risk factors exist.
- **Chest:**
- Narrowing of the airways
- Blocked blood vessel in the lung
- Wheezing, Cough, Feeling breathless.
- **Stomach and gut:**
- Diarrhoea
- Stomach pain
- Feeling sick or being sick
- **Skin and tissue:**
- Itching
- Nettle-rash on the entire body
- Swelling of the face, tongue and lips
- **Injection site/General:**
- Chest pain and discomfort
- Chills or feeling hot
- Fever
- Generally feeling unwell
- Pain.
- **Investigations:**
- increased levels of fibrin D-dimer in blood *(a small protein fragment that is made when your body is making or breaking up blood clots)*

Other side effects:
- Rapid intravenous infusion can cause stabbing pain and a feeling of numbness in the face, arms or legs, as well as a drop in blood pressure.

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
The Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Malta
ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

5. How to store FEIBA
- Keep out of the sight and reach of children.
- Do not use FEIBA after the expiry date which is stated on the label after 'EXP'. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Do not freeze.
- Store in the original package, to protect from light.
- FEIBA must not be used if the vials are damaged.
- Do not use if the device or its packaging are damaged or show any sign of deterioration.
- The solution should only be used once.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What FEIBA contains
Powder
- The active substance is factor VIII inhibitor bypassing activity.
- 1 ml contains 50 U/ml factor VIII inhibitor bypassing activity.
    - The presentation 500 U FEIBA contains 500 U (Units) factor VIII inhibitor bypassing activity in 200 – 600 mg human plasma protein
    - The presentation 1000 U FEIBA contains 1000 U (Units) factor VIII inhibitor bypassing activity in 400 – 1,200 mg human plasma protein
    - The presentation 2500 U FEIBA contains 2500 U (Units) factor VIII inhibitor bypassing activity in 1,000 – 3,000 mg human plasma protein.
- FEIBA also contains factors II, IX and X, mainly in non-activated form as well as activated factor VII. Factor VIII coagulant antigen (F VIII C:Ag) and the factors of the kallikrein-kinin system are present only in trace amounts, if at all.
- The other ingredients are sodium chloride and sodium citrate.

Solvent
Water for Injections.

What FEIBA looks like and contents of the pack
The product is presented as a white to off-white or pale green freeze-dried powder or friable solid .
Powder and solvent come in vials made of glass both closed with rubber stoppers.

Contents:
- 1 vial with 500 U, 1000 U or 2500 U FEIBA powder for solution for infusion
- 1 vial with 10 ml, 20 ml or 50 ml Water for Injections
- 1 BAXJECT II Hi-Flow

Marketing Authorisation Holder and Manufacturer

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BaxJect II Hi-Flow Device
The device is sterilized by gamma irradiation.
It is for single use only.
The device is latex free.

Do not use if package is damaged

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