FEIBA-NF

Factor VIII inhibitor bypassing fraction, 500, 1000, 2500 IU /vial

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about the FEIBA-NF. It does not contain all of the available information. All medicines have risks and benefits. Your doctor has weighed the risks against the benefits of using FEIBA-NF for you.

It does not take the place of talking to your doctor or pharmacist. If you have any concerns about having this medicine, ask your doctor or pharmacist.

What FEIBA-NF is used for

FEIBA-NF is used for the treatment and prevention of bleeding in haemophilia A and B patients who have developed inhibitors (antibodies) against coagulation factor VIII (FVIII), and factor IX (FIX) respectively.

How does FEIBA-NF work?

Under normal physiological conditions, FVIII and FIX are essential for blood clotting and therefore the control of bleeding. Individuals with haemophilia A have decreased FVIII in their blood circulation, and individuals with haemophilia B have decreased levels of FIX. These deficiencies may lead to heavy bleeding into joints, muscles or internal organs, either spontaneously or as a result of accidental or surgical trauma.

FVIII and FIX replacement therapy have been successfully used for the treatment of haemophilia A and haemophilia B. However, some haemophilia A and haemophilia B patients develop antibodies against FVIII and FIX, respectively, in the course of their treatment, leading to replacement therapy becoming ineffective. FEIBA-NF can bypass the effects of these antibodies, thus normalizing the blood clotting process.

FEIBA-NF is a mixture of coagulation factors that converts pro-thrombin to thrombin in the coagulation pathway without the need for FVIII or FIX. FEIBA stands for Factor Eight Inhibitor Bypassing Activity.

Before you are given FEIBA-NF

FEIBA-NF should not be given to you if:

- you have a tendency to develop allergic reactions or are hypersensitive to any human plasma-derived product. Some of the symptoms of an allergic reaction may include skin rash, shortness of breath, swelling of the face, lips or tongue, which may cause difficulty swallowing;
- you are suffering from a generalised blood clotting disorder (Disseminated Intravascular Coagulation or DIC) resulting from an excessive activation of the blood clotting system. DIC usually occurs in connection with severe disease, injury, or a major operation, and is diagnosed by a laboratory test;
- you have a history of angina or heart attacks, or currently have a severe clot (thrombosis or embolism);
- the expiry date printed on the pack has passed.

You must tell your doctor if you:

- are suffering from liver damage;
- are on a low sodium diet;
- have any other illness;
- are taking any other medicines purchased from a pharmacy, health food store or supermarket. Some medicines and FEIBA-NF may interfere with each other.

You must tell your doctor if you are pregnant, planning to become pregnant or breast-feeding.
Although haemophilia is very rare in women, the use of FEIBA-NF during pregnancy or breast-feeding is not recommended, due to insufficient information being available. It should only be used in these situations if clearly needed.

How FEIBA-NF is given

- **How much is given:**
  Your doctor will decide how much FEIBA-NF will be given to you. Each individual will receive a different dosage, which may vary between treatments. The dose you receive will be based on:
  (a) body weight;

(b) how much, how often and which sites (knees, muscle, etc) bleeding occurs;
As a general guide a dose of 50 to 100 Units per kg body weight is recommended. However, a daily dose of 200 U/kg body weight should not be exceeded. Since the response to treatment may differ from patient to patient the dosage recommendations are only guidelines.

- **Method of Administration (use aseptic technique):**
FEIBA-NF is usually administered in a hospital. However, some individuals may be trained to use FEIBA-NF at home. It is administered by intravenous injection.
Do not attempt to self administer the product unless you have received proper training on how to use the product by your doctor or other competent healthcare professional, e.g a haemophilia nurse. If you are unsure about how to use this medicine contact your doctor or competent healthcare professional to seek advice.
If you have been trained to inject at home, take the dry medicine vial and the small vial of water out of the refrigerator and let them come to room temperature (15°C to 30°C). Visually examine the dry medicine vial and contents, and do not use if there is any sign of damage or discolouration. The dry medicine should normally appear off-white to faint yellow.
After preparation, the medicine should be used immediately or at least within 3 hours after it is prepared. Do not refrigerate after reconstitution. Please refer to the directions on the package or talk to your doctor.
Do not reuse syringes and needles. Place them in a puncture resistant disposable container, or otherwise dispose of them as directed by your doctor.
Likewise, discard any unused solution as directed by your doctor.
- **Case of overdose**
Overdosage of FEIBA-NF may increase the risk of adverse reactions, such as blood clots, or a heart attack. In such cases administration of the product should be stopped immediately. As the product will be given to you in a hospital setting by a trained healthcare professional, the chances of you receiving an overdose are remote.
- **Before travelling**
Talk to your doctor before travelling, and ensure you have enough FEIBA-NF with you to cover the time of travelling. It is important to obtain a written statement from your doctor, explaining the reasons why you need to have this medicine and injecting device with you, otherwise you may not be allowed to bring it into the country of travelling. Please ensure you have multiple copies of the letter if travelling to more than one country.

What are the possible side effects of FEIBA-NF?

If any of the following side effects occur, these may mean that you are having a severe allergic response to the medicine: fast or irregular breathing, shortness of breath, troubled breathing, tightness in the chest and/or wheezing, changes in facial skin colour, puffiness or swelling of the eyelids or around the eyes, skin rash, hives, itching.

If any of such allergic reactions occur during the administration of FEIBA-NF, the infusion should be stopped immediately, and you should contact your doctor or present yourself in an emergency department of a hospital to seek further treatment.
If you experience allergic reactions your doctor will prescribe an appropriate medication, such as antihistamine. In the rare case of severe hypersensitivity reactions your doctor will follow the current guidelines of shock treatments.

In the course of treatment with FEIBA-NF, blood clots may occur, particularly after high doses and/or in patients with other risk factors for developing blood clots. A generalised blood clotting disorder (Disseminated Intravascular Coagulation, DIC) has been observed in some cases.

In very rare cases heart attack (myocardial infarction) has occurred after high doses and/or prolonged administration in the presence of risk factors predisposing to heart disease.

Other adverse effects that may occur include fever, chills, muscle pains and nausea.

FEIBA-NF is manufactured from donated blood. There is a small risk that such products may transmit infections such as viral infections.

Other side effects not listed above may occur in some patients. Please tell your doctor or pharmacist of any suspected undesirable effect that is not mentioned in this leaflet.

Do not be alarmed by this list of possible side effects, you may not experience any of them.

Instructions for Reconstitution of FEIBA-NF

Do not attempt to do an infusion to yourself unless you have been taught how by your healthcare provider or haemophilia center.
Always follow the specific instructions given by your healthcare provider. The steps listed below are general guidelines for using your medicine. If you are unsure of the procedures, please call your healthcare provider before using.

Reconstitution of the powder for injection

1. Warm solvent (sterilised water for injections) vial to room temperature (15°C-25°C), for example by using a water bath for several minutes (max. 37°C).
2. Remove the protective caps from the FEIBA-NF 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-NF vial stopper. The vacuum will draw the solvent into the FEIBA-NF vial (Fig. d).
6. Swirl gently until all material is dissolved. Ensure that FEIBA-NF is completely dissolved; otherwise active material will not pass through the device filter.

Figure a

Figure b

Figure c

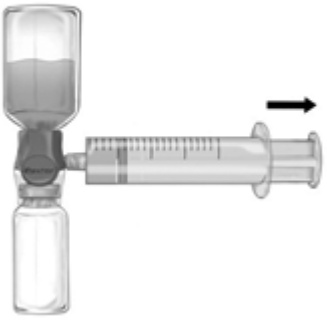
Injection/Infusion

1. Remove the blue cap from BAXJECT II Hi-Flow. Take the syringe and connect it to BAXJECT II Hi-Flow (DO NOT DRAW AIR INTO THE SYRINGE) (Fig. e).
2. Invert the system (with FEIBA-NF vial on top). Draw the FEIBA-NF solution into the syringe by pulling the plunger back slowly (Fig. f).
3. Disconnect the syringe.
4. Slowly inject the solution intravenously with a winged set for injection (or a disposable needle).

Figure d

Figure e

Figure f



Product descriptions

What FEIBA-NF looks like?

It is a white-to-cream-coloured powder in a single-dose glass vial accompanied by sterile water-for-injection in a glass vial for reconstitution. The package also contains a Baxject II Hi-Flow reconstitution device and a package insert.

What is in FEIBA-NF?

The active ingredient in FEIBA-NF is human plasma-derived protein with factor VIII inhibitor bypassing activity expresssed. Each reconstituted vial contains 200-600 mg (500 Units), 400-1200 mg (1000 Units) or 1000-3000 mg (2500 Units) of factor VIII inhibitor bypassing fraction. It also contains factors II, IX and X mainly in a non-activated form. Each reconstituted vial also contains sodium chloride and sodium citrate. The solvent vial contains sterile water for injection.

How to store FEIBA-NF

FEIBA-NF will usually be stored in a hospital pharmacy. The vials can be stored at room temperature (below 25°C). Under these conditions it has a shelf life of 2 years. After reconstitution, it should not be refrigerated and must be administered within 3 hours. Avoid freezing to prevent damage to the diluent bottle.

Where can you get more information?

You can get more information from your doctor or pharmacist.

Name and address of the sponsor

Baxalta Australia Pty Ltd
1 Baxter Drive
Old Toongabbie, NSW 2146.

AUST R 104896 (500U), 104911 (1000U), 172236 (2500U)

Date of most recent amendment: May 2015