FEIBA® NF

Factor VIII inhibitor bypassing fraction powder for injection with diluent vials (500, 1000, 2500 U/vial)

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before you start using FEIBA NF.

This leaflet answers some common questions about the FEIBA NF. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks against the benefits of using FEIBA NF for you.

If you have any concerns about having this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

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.

It is possible that your doctor may give you FEIBA NF for another reason.

Ask your doctor if you have any questions about why you are being given FEIBA NF.

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.

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.

In patients with acquired haemophilia (non-haemophiliacs), some of these coagulation factors are not working properly because the patient has developed antibodies to his/her own coagulation factors.

FVIII and FIX replacement therapy have been successfully used for the treatment of haemophilia A and haemophilia B as well as non-haemophiliacs. FEIBA NF can bypass the effects

of these antibodies, thus normalising 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. Factor VII is present in FEIBA NF mainly in the activated form, and factors II, IX, and X are present mainly in the non-activated form. 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;

- the packaging is torn or show sign of tampering.

You must tell your doctor if you:

- have liver problems;
- have suffered a heart attack;
- have a blood clot;
- are on a low sodium diet;
- have any other illness causing your immune system not to work properly.

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 breastfeeding is not recommended, due to insufficient information being available. It should only be used in these situations if clearly needed.

If you have not told your doctor about any of the above, tell them before you start using FEIBA NF.

If you are, or may be allergic to FEIBA NF or any of its ingredients, and your doctor is aware of this, it is possible that your doctor may give you FEIBA NF if no alternative treatment is available. Your doctor will only do so after careful weighing of the expected benefits and the risks of using the product.

Taking other medicines

Tell your doctor or pharmacist if you are using any other medicines including any that you obtained without a

prescription from your pharmacy, supermarket or health food shop.

Some medicines and FEIBA NF may interfere with each other. These include:

- any medicines which help make blood clots more stable and last longer (these are known as anti-fibrinolytics), for example tranexamic acid, aminocarproic acid, recombinant factor VIIa;

- emicizumab (which is used to prevent bleeding in haemophilia A patients who have inhibitors to FVIII).

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

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 amount, which may vary between treatments. The dose you receive will be based on:

- body weight;

- how much, how often and in which sites bleeding occurs (knees, muscle, etc.).

As a general guide a dose of 50 to 100 Units per kg (U/kg) body weight is recommended.

The maximum single dose should not be more than 100 U/kg.

The maximum 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. Some individuals may be trained to use FEIBA NF at home.

FEIBA NF is given by a slow injection or infusion directly into your vein.

Do not attempt to inject FEIBA NF by yourself 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.

Before injecting FEIBA NF, take the vials out of the refrigerator and let them come to room temperature.

Do not mix FEIBA NF with any other medicines or solvent other than the water for injections supplied with the pack.

Always inspect the solution after it is prepared for use and before injection.

The solution should be clear to slightly off white to faint yellow.

Do not inject if the solution is discoloured or cloudy or contains particles.

Use the solution straight away or within 3 hours after it is prepared.

Do not refrigerate the solution after it is prepared.

Use a new syringe and needle for each injection.

Instructions for using FEIBA NF

Always follow the specific instructions given by your healthcare provider.

The steps listed below are general guidelines for using your medicine.

Ask your healthcare provider before using FEIBA NF if you are unsure of the procedures.

FEIBA NF is provided as a powder (in a single-dose vial) and water for injections (in a diluent vial). The water for injection in the diluent vial is used as a solvent to dissolve the powder.

Preparing FEIBA NF for injection

1. Warm the vials to room temperature, for example by using a water bath for several minutes (max. 37°C).

2. Remove the protective caps from the powder vial and diluent vial and clean 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. Do not remove the device from the package.

4. Turn the package over and insert the clear plastic spike through the diluent stopper. Grip the package at its edge and pull the package off BAXJECT II Hi-Flow. Do not remove the blue cap from BAXJECT II Hi-Flow device.

5. With BAXJECT II Hi-Flow attached to the diluent vial; invert the system so that the diluent vial is on top of the device. Insert the purple plastic spike through the powder vial stopper. The vacuum will draw the solution into the powder vial at the bottom.

6. Swirl gently until all powder is dissolved. Make sure the powder is completely dissolved or otherwise the undissolved powder will not pass through the device filter.

Injecting a dose

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).

2. Invert the system (with the vial now containing the solution on top). Draw the solution into the syringe by pulling the plunger back slowly.

3. Disconnect the syringe.

4. Slowly inject the solution into your vein with a winged set for injection (or a disposable needle)

If you use too much (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 most likely be given to you in a hospital setting by a trained healthcare professional, the chances of you receiving an overdose are remote.

Immediately telephone your doctor or the Poisons Information Centre (telephone 131 126), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have been given too much FEIBA NF.

Do this even if there are no signs of discomfort or poisoning.

While you are using FEIBA NF

Things you must do

Monitor your bleeding and tell your doctor or nurse if your bleeding gets worse.

You will have your blood tested regularly to see how your treatment is working. If FEIBA NF does not 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 of platelets affects how well FEIBA NF works.

If you are about to have any blood test for red cell antibodies or hepatitis, tell your doctor that you are using FEIBA NF.

FEIBA NF may interfere with some of these blood tests leading to inaccurate results.

Talk to your doctor before travelling, and make sure 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. Make sure you have multiple copies of the letter if travelling to more than one country.

Things you must not do

Do not give FEIBA NF to anyone else, even if they have the same condition as you.

Do not stop using FEIBA NF, or adjust the dosage, without checking with your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after using FEIBA NF.

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Your risk of getting side effects is increased if you are given high doses of FEIBA NF.

You may need medical attention if you get some of these side effects.

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

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- dizziness;

- headache;
- light-headedness (or any other sign of low blood pressure);
- rash.

The above list includes the common side effects of FEIBA NF.

If any of the following happen, tell your doctor immediately or go to Emergency at the nearest hospital:

- shortness of breath; wheezing; difficulty breathing; chest pain or discomfort;
- changes in facial skin colour, puffiness or swelling of your face, lips, tongue, or other parts of the body, rash or hives.

The above list includes serious side effects of FEIBA NF which may occur if you are having a severe allergic response to the medicine. If any of the above occurs during the FEIBA NF injection, stop the injection immediately.

You may need urgent medical attention or hospitalisation.

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 patients who have pre-existing risk factors for developing heart disease, heart attack (myocardial infarction) has been

reported after using high doses and/or being treated for a long time.

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

Tell your doctor or pharmacist of any suspected undesirable effect that is not mentioned in this leaflet.

Other side effects not listed above may occur in some patients.

After using FEIBA NF

Storage

All medicines should be kept where children cannot reach them.

Store FEIBA NF below 25°C. Protect from light.

Do not freeze FEIBA NF.

Keep the FEIBA NF in the pack until it is time to use it.

This will protect the vials from light. If the vials are not stored in the pack, the product may not keep well.

Unopened vials stored in the pack can be kept below 25°C until its expiry date which is printed on the packaging.

Do not store the solution in the fridge after the powder is mixed with the diluent.

Use the solution straight away, or within 3 hours after it is prepared.

Disposal

FEIBA NF is for single use in single patient only.

Discard any solution left in the vial at the end of your injection or infusion.

Dispose the used vials and all materials in an appropriate container.

If your doctor tells you to stop using FEIBA NF or the expiry date has passed, ask your pharmacist or your Haemophilia Treatment Centre what to do with any medicine that is left over.

Ask your doctor, pharmacist or Haemophilia Treatment Centre if you have any questions about how to dispose FEIBA NF.

Product descriptions

What FEIBA NF looks like

FEIBA NF comes as a white-to-cream-coloured powder in a single-dose glass vial.

Each pack contains:

- 1 vial of FEIBA NF powder for injection;

- 1 vial of water for injection (diluent to dissolve the powder for injection);
- 1 BAXJECT II Hi-Flow reconstitution device; and
- a package insert.

FEIBA NF is available in the following strengths:

- 500 Units (containing 200-600 mg of the active ingredient in each vial), for reconstitution with either 10 mL or 20 mL diluent;
- 1000 Units (containing 400-1200 mg of the active ingredient in each vial), for reconstitution with 20 mL diluent;
- 2500 Units (containing 1000-3000 mg of the active ingredient in each vial), for reconstitution with 50 mL diluent.

Ingredients

Active ingredient:

- human plasma-derived protein with factor VIII inhibitor bypassing activity expressed.

Inactive ingredients:

- sodium chloride;
- sodium citrate dihydrate;

- water for injections (diluent).

Sponsor

FEIBA NF is supplied in Australia by:

Takeda Pharmaceuticals Australia Pty Ltd

Level 39, 225 George Street

Sydney NSW 2000

Australia

Telephone: 1800 012 612

www.takeda.com/en-au

Australian registration numbers

AUST R 104896 (500 U)

AUST R 104911 (1000 U)

AUST R 172236 (2500 U)

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