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PATIENT INFORMATION LEAFLET

FEIBA 500 U and 1000 U Powder and Solvent for Solution for Infusion

Baxter

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Read all of this leaflet carefully before you are given this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

Throughout this leaflet FEIBA 500 U and 1000 U 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. BEFORE YOU USE FEIBA

Do not use FEIBA if:
- You are allergic (hypersensitive) to the active ingredients or any of the other ingredients (listed in section 6). The signs of an allergic reaction are shortness of breath, wheezing, rash, itching or swelling of your face and lips.
- 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, nurse or pharmacist before using FEIBA.

Take special care with FEIBA

Check with your doctor, nurse or pharmacist before using FEIBA if:
- You have liver problems
- You have suffered a heart attack
- You have a blood clot (thrombosis or embolism)
- Your immune system isn't working properly
- You are on a low sodium diet.

Using other medicines

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

In particular, tell your doctor, nurse or pharmacist if you are taking any of the following medicines, they may affect the way FEIBA works:
- Medicines used to breakdown blood clots called 'clot-busting' or 'fibrinolytic medicines', such as epsilon-aminocaproic acid. If your doctor tells you that you must have treatment with these drugs and FEIBA, they should leave at least 6 hours between having either one.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, think you might be pregnant or are trying to become pregnant.
- 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.

Do not breast-feed while being treated with FEIBA.

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.

Important information about some of the ingredients of FEIBA

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 the blood 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).

The risk of infectious diseases caused by some other viruses cannot be totally ruled out, because the steps taken are less effective against them. One such virus is parvovirus B19. Parvovirus B19 infection may be serious for pregnant women (because of infection to the unborn child) and for people whose immune system does not work properly or who have certain types of anaemia, such as sickle cell or haemolytic anaemia.

Vaccines you may have with FEIBA

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.

3. HOW FEIBA IS GIVEN

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, 50 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**
- 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.
- When you have mixed the powder with sterile water (Water for Injections), use it immediately.
- For administration the use of a luer lock syringe is recommended.
- Any unused solution must be disposed of appropriately.

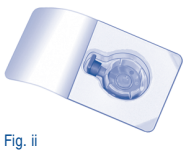
- This medicine must not be mixed with other medicines or solvents.
- Inject FEIBA solution in the way that you have been trained.

Dissolving the dried substance

When you have mixed the powder with sterile water use it immediately. Please see the diagrams below.

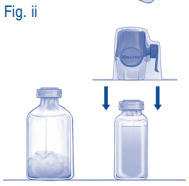
1. Warm the powder and sterile water vials to room temperature (15°C – 25°C) if necessary.
2. Remove the protective caps from the powder and sterile water vials and cleanse the rubber stoppers of both with alcohol swabs. Place the vials on a flat surface.

Fig. i



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.**

Fig. ii



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 sterile water 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.

Fig. iii

5. With the device attached to the sterile water vial, invert the system so that the sterile water vial is on top of the device. Insert the purple plastic spike through the powder vial stopper. The vacuum will draw the sterile water into the powder vial (Fig. iv).

Fig. iv

6. Swirl gently until all the material is dissolved. Ensure that the powder is completely dissolved, otherwise active material will not pass through the device filter.

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

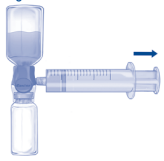
Injecting the dissolved product

For administration the use of a luer lock syringe is recommended.

Fig. v

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).

Fig. vi



3. Disconnect the syringe.
4. Slowly inject the solution intravenously with a winged set for injection (or a disposable needle).

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 about DIC.

4. POSSIBLE SIDE EFFECTS

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

Tell your doctor, nurse or pharmacist straight away if you notice any of the following side effects. Sometimes they can be serious. The infusion may also need to be stopped:

- Feeling dizzy or lightheaded due to changes in your blood pressure, changes in your pulse rate, breathing problems, chest pain or cough.
- Signs of allergy such as rash, itchy skin, swelling of your face, lips or tongue, shortness of breath, wheezing (anaphylactic shock). If you have experienced allergic reactions to plasma derivatives in the past, your doctor may prescribe anti-histamines to help prevent it happening again.

Other possible side effects include:

- Fever (high temperature)
- Pain at the injection site or tingling or pins and needles
- Heart attack after high doses or when given for a long time when other risk factors exist
- Blood clots in your circulation. Signs may include pains in your legs or other places, difficulty breathing or stroke.

If you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or nurse straight away.

5. HOW TO STORE AND HANDLE FEIBA

- Keep out of the reach and sight of children.
- Do not store above 25°C.
- Do not freeze.
- Keep the vials in the outer carton to protect from light.
- 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.
- 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.

6. FURTHER INFORMATION

What FEIBA contains

- The active substance is Human Plasma Protein 200 to 600 mg or 400 to 1200 mg with a Factor VIII Inhibitor Bypassing Activity of 500 units or 1000 units.
- The other ingredients are sodium chloride and sodium citrate.
- A vial of Water for Injections is also provided.

What FEIBA looks like and contents of the pack

It is supplied as a white to pale green dry substance together with a vial of Water for Injections to make a solution.

FEIBA is available in sizes of 500 and 1000 units, to be dissolved in 20ml of sterile water. Each pack also includes a device for reconstitution.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation holder is:
Baxter Healthcare Ltd
Caxton Way, Thetford, Norfolk
IP24 3SE

Send all enquiries to this address.

FEIBA is made at:
Baxter AG
Vienna, Austria

This leaflet was last approved in September 2010

Is this leaflet hard to see or read?

Telephone 01635 206345 for an audio-tape, large print leaflet or other formats.

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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