PACKAGE LEAFLET: INFORMATION FOR THE USER

Fanhdi 250, 500 and 1000 IU, powder and solvent for solution for injection

Human coagulation factor VIII, Ph.Eur.

Please read 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.

What is in this leaflet:

1. What Fanhdi is and what it is used for

Fanhdi is supplied as a powder for solution for injection containing 250, 500 or 1000 IU of human coagulation factor VIII per vial. (Note IU stands for international unit, a standard measure of activity).

Once reconstituted with the appropriate amount of solvent (water for injections), each vial contains 25, 50 or 100 IU of FVIII/ml.

Fanhdi is one of the group of medicines called clotting factors.

Fanhdi is used for the treatment and prevention of bleeding in patients with haemophilia A (congenital factor VIII deficiency).

This product may be used in the management of acquired factor VIII deficiency.

No data is available to recommend the use of Fanhdi in von Willebrand disease.

2. What you need to know before you use Fanhdi

Do not use Fanhdi

- If you are allergic to human coagulation factor VIII or to any of the other ingredients of this medicine (listed in section 6).

- If you have not been fully trained how to inject yourself by your doctor or haemophilia nurse.

If you want more detailed information then ask your doctor.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Fanhdi.

- Rarely you may have an anaphylactic reaction (a sudden severe allergic reaction) such as rash, tightness of the chest, dizziness, vertigo or nausea, or feeling dizzy when you are standing. If these symptoms occur, you must **stop using** the product **immediately** and contact your doctor.

- Your doctor should perform some tests to make sure that the dosage of Fanhdi you are receiving is enough to achieve and maintain appropriate Factor VIII levels and thus stop any bleeding.

- The formation of inhibitors (antibodies) is a known complication that can occur during treatment with all Factor VIII medicines. These inhibitors, especially at high levels, stop the treatment working properly and you or your child will be monitored carefully for the development of these inhibitors. If your or your child's bleeding is not being controlled with Fanhdi, tell your doctor immediately.

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,
- the testing of each donation and pools of plasma for signs of virus/infections,
- the inclusion of 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.

The measures taken are considered effective for enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus and hepatitis C virus, and for the non-enveloped hepatitis A virus. The measures taken may be of limited value against non-enveloped viruses such as parvovirus B19.

Parvovirus B19 infection may be serious for pregnant women (foetal infection) and for individuals whose immune system is depressed or who have some types of anaemia (e.g. sickle cell disease or haemolytic anaemia).

Your doctor should recommend that you consider vaccination against hepatitis A and B if you regularly/repeatedly receive human plasma-derived factor VIII products.

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

See also section 4.

Other medicines and Fanhdi

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

No interactions of Fanhdi with other medicines are known.

Do not mix Fanhdi with any other medicines that you receive by injection.

Pregnancy and breast-feeding

Based on the rare occurrence of haemophilia A in women, experience regarding the use of human coagulation factor VIII during pregnancy and breast-feeding is not available.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Fanhdi has little or none effect on your ability to drive and use machines.

Sodium content

The residual content of sodium in Fanhdi, arising from the manufacturing process, does not exceed 23 mg per vial. This is equivalent to 1.15% of the recommended maximum daily intake of sodium for an adult. However, depending on the body weight of the patient and the posology, the patient may receive more than one vial.

3. How to use Fanhdi

Reconstitute the product as described at the end of this leaflet (please see pictograms on the back of the leaflet). The product must be given by intravenous route. The administration rate should be 3 ml/min and never more than 10 ml/min to avoid undesirable side effects.

The amount of Fanhdi you should use depends on many factors, such as your weight, your clinical status and the type and severity of bleeding. Your doctor will calculate the dose, the frequency and the intervals of administration of Fanhdi in order to reach the necessary level of Factor VIII in your blood.

Your doctor will tell you the duration of your treatment with Fanhdi.
You will be given full training before using Fanhdi without the hospital supervision. Please refer to all your training materials or contact your local haemophilia centre for more information.

You should not self-administer Fanhdi alone: always have a responsible adult present.

Use in children and adolescents

There are insufficient data from clinical trials to recommend the **use of Fanhdi in children** less than 6 years of age.

If you use more Fanhdi than you should

No cases of overdose with Fanhdi have been reported. However, if you have used Fanhdi more than required, consult your doctor or pharmacist immediately.

If you forget to use Fanhdi

Proceed immediately with the following dose and continue at regular intervals as directed by your doctor. Do not take a double dose to make up for a forgotten dose.

If you stop using Fanhdi

Do not stop using Fanhdi without consulting your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

On rare occasions, you may have some of the following side effects after the administration of Fanhdi. Please **contact your doctor immediately** if you experience:

- itching, local reactions at the injection site (e.g. burning and transitory reddening)
- allergic reactions (e.g. tightness of the chest/feeling unwell, dizziness, nausea and slight drop of blood pressure than can make you feel dizzy when you are standing)
- peculiar taste in your mouth
- fever
- faster heart beat (tachycardia)

Occasionally an **anaphylactic shock** may occur. If you observe any of the following symptoms during the injection/perfusion, interrupt the injection/perfusion and **contact your doctor immediately**:

- tightness of the chest/feeling unwell
- dizziness
- slight hypotension (slight drop of blood pressure with dizziness when you are standing)
- nausea

Allergic reactions to the components of the product cannot be totally excluded. For children not previously treated with Factor VIII medicines, inhibitor antibodies (see section 2) may form very commonly (more than 1 in 10 patients); however patients who have received previous treatment with Factor VIII (more than 150 days of treatment) the risk is uncommon (less than 1 in 100 patients). If this happens your or your child's medicines may stop working properly and you or your child may experience persistent bleeding. If this happens, you should contact your doctor immediately.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fanhdi

Keep this medicine out of the sight and reach of children.

Do not store above 30 ºC. Do not freeze.

Do not use this medicine after the expiry date which is stated on the vial label and carton after EXP.

Do not use this medicine if you notice the solution is cloudy or has deposits. Generally the solution is clear or slightly opalescent. If the solution is discoloured or cloudy discard it.

After reconstitution the product is physically and chemically stable for 12 hours at 25 ºC. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are responsibility of the user and would normally not be longer than 24 hours at 2 to 8 ºC, unless reconstitution has taken place in a controlled and sterile environment.

Any unused product or waste material should be disposed of in accordance with local requirements.

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 Fanhdi contains

The active substance is human coagulation factor VIII.

Fanhdi is presented as powder for solution for injection containing 250, 500 or 1000 IU human coagulation FVIII per vial. The product is reconstituted with 10 ml of water for injections.

The other ingredients are albumin, histidine and arginine.

What Fanhdi looks like and contents of the pack

Vial containing white or pale yellow powder and syringe with water for injections (solvent).

Presentations:

Fanhdi 250 IU	PA0849/001/001
Fanhdi 500 IU	PA0849/001/002
Fanhdi 1000 IU	PA0849/001/003

Pack size: 1 lyophilised vial, 1 syringe pre-filled with solvent and accessories (vial adaptor, filter, 2 alcohol swabs and butterfly needle).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Instituto Grifols, S.A.
Can Guasc, 2 - Parets del Vallès
08150 Barcelona - SPAIN

This leaflet was last revised in 12/2017

Instructions for use/handling

Follow these instructions unless otherwise indicated by your doctor.

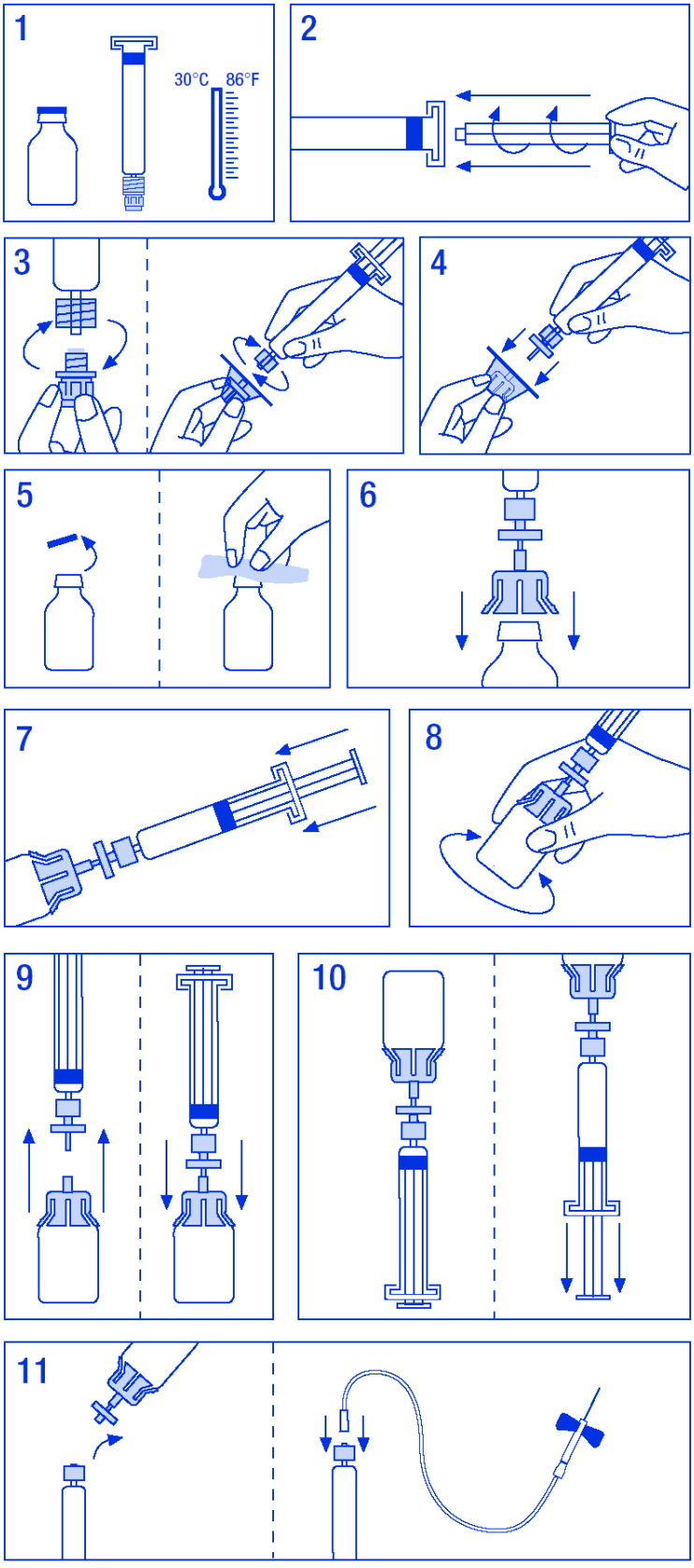
Left-over product must never be kept for later use, nor stored in a refrigerator.

To prepare the solution:

1. Warm the vial and syringe but not above 30 ºC.
2. Attach plunger to syringe containing solvent.
3. Remove filter from packaging. Remove cap from syringe tip and attach syringe to filter.
4. Remove vial adaptor from packaging and attach to syringe and filter.
5. Remove cap from vial and wipe stopper with swabs provided.
6. Pierce vial stopper with adaptor needle.
7. Transfer all solvent from syringe to vial.
8. Gently shake vial until all product is dissolved. As with other parenteral solutions, do not use if product is not properly dissolved or particles are visible.

9. Briefly separate the syringe/filter from vial/adaptor, to release the vacuum.
10. Turn the vial upside down and draw the solution into the syringe.
11. Prepare injection site, separate syringe and inject product using the butterfly needle provided. Injection rate should be 3 ml/min into a vein and never more than 10 ml/min to avoid vasomotor reactions.

Do not re-use administration sets.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