

Package Leaflet: Information for the user

Jivi 500 IU powder and solvent for solution for injection

Jivi 1000 IU powder and solvent for solution for injection

Jivi 2000 IU powder and solvent for solution for injection

PEGylated B-domain deleted recombinant human coagulation factor VIII (damoctocog alfa pegol)

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Jivi is and what it is used for
2. What you need to know before you use Jivi
3. How to use Jivi
4. Possible side effects
5. How to store Jivi
6. Contents of the pack and other information

1. What Jivi is and what it is used for

Jivi contains the active substance damoctocog alfa pegol. It is produced by recombinant technology without addition of any human- or animal-derived components in the manufacturing process. Factor VIII is a protein naturally found in the blood that helps to clot it. The protein in damoctocog alfa pegol has been modified (pegylated) to prolong its action in the body.

Jivi is used to **treat and prevent bleeding** in previously treated adults and adolescents aged from 12 years with haemophilia A (hereditary factor VIII deficiency). It is not for use in children younger than 12 years of age.

2. What you need to know before you use Jivi

Do not use Jivi if you are

- allergic to damoctocog alfa pegol or any of the other ingredients of this medicine (listed in section 6).
- allergic to mouse or hamster proteins.

Warnings and precautions

Talk to your doctor or pharmacist if you have

- tightness in the chest, fall in blood pressure (often shown by feeling dizzy when getting up quickly), itchy nettle-rash, wheezing, feeling sick or faint. These may be signs of a rare severe **sudden allergic**

reaction to this medicine. **Stop injecting the product** immediately and get medical help at once if this occurs.

- bleeding that is not being controlled with your usual dose of this medicine. Speak with your doctor immediately if this occurs. You may have developed antibodies against factor VIII (inhibitors) or antibodies against polyethylene glycol (PEG). These make Jivi less effective at preventing and controlling bleeding. Your doctor may carry out tests to confirm this and ensure that your Jivi dose provides adequate factor VIII levels. Your doctor may switch you back to your previous factor VIII treatment, if needed.
- previously developed factor VIII inhibitors to a different product.
- heart disease or you are at risk of heart disease.
- to use a central venous access device for this medicine. You may be at risk of device-related complications where the catheter is inserted including:
 - local infections
 - bacteria in the blood
 - a blood clot in the blood vessel

Children

Jivi is not for use in children younger than 12 years of age.

Other medicines and Jivi

Jivi is not known to influence or be influenced by other medicines. Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

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 using this medicine.

Driving and using machines

Jivi has no influence on your ability to drive and use machines.

Jivi contains sodium

This medicine contains less than 1 mmol (23 mg) sodium per dose, and is therefore considered to be essentially 'sodium-free'.

3. How to use Jivi

Treatment with Jivi will be started by a doctor who is experienced in the care of patients with haemophilia A. After suitable training patients or carers may be able to give Jivi at home. Always use this medicine exactly as described in this leaflet and as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The dose of factor VIII units is measured in International Units (IU).

Treatment of bleeding

To treat a bleed, your doctor will calculate and adjust your dose and how often it should be given, depending on factors such as:

- your weight
- the severity of your haemophilia A
- where the bleeding is and how serious it is
- whether you have inhibitors and how high their level is
- the factor VIII level that is needed.

Prevention of bleeding

To prevent bleeding your doctor will select an appropriate dose and frequency depending on your need:

- 45–60 IU per kg body weight every 5 days or
- 60 IU per kg body weight every 7 days or
- 30–40 IU per kg body weight two times per week.

Laboratory tests

Laboratory tests at suitable intervals help to ensure you always have adequate factor VIII levels. For major surgery in particular, your blood clotting must be closely monitored.

Duration of treatment

Usually Jivi treatment for haemophilia is needed lifelong.

How Jivi is given

Jivi is injected into a vein over 2 to 5 minutes depending on the total volume and your comfort level. The maximum rate is 2.5 mL per minute. Jivi should be used within 3 hours after reconstitution.

How Jivi is prepared for injection

Use only the components (vial adapter, pre-filled syringe containing solvent and venipuncture set) provided with each package of this medicine. Please contact your doctor if these components cannot be used. Do not use if any component of the package is opened or damaged.

The reconstituted product must be **filtered by using the vial adapter** before injection to remove any possible particles in the solution.

This medicine must **not** be mixed with other injections. Do not use solutions that are cloudy or contain visible particles. Follow the **instructions for use** given by your doctor and provided **at the end of this leaflet**.

If you use more Jivi than you should

Tell your doctor if this occurs. No symptoms of overdose have been reported.

If you forget to use Jivi

Inject your next dose immediately and continue at regular intervals as advised by your doctor. Do not use a double dose to make up for a forgotten dose.

If you stop using Jivi

Do not stop using this medicine without checking with your doctor.

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

4. Possible side effects

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

The most **serious** side effects are **allergic reactions** or severe allergic reaction. **Stop injecting Jivi immediately and speak to your doctor at once if such reactions occur.** The following symptoms could be an early warning of these reactions:

- chest tightness/general feeling of being unwell
- burning and stinging at the application site
- nettle-rash, flushing
- a reduction in blood pressure, which may make you feel faint upon standing

- feeling sick (nausea)

For patients who have received previous treatment with factor VIII (more than 150 days of treatment) inhibitor antibodies (see section 2) may form uncommonly (less than 1 in 100 patients). If this happens your medicine may stop working properly and you may experience persistent bleeding. If this happens, you should contact your doctor immediately.

The following side effects may occur with this medicine:

Very common (may affect more than 1 in 10 people):

- headache

Common (may affect up to 1 in 10 people):

- stomach pain
- nausea, vomiting
- fever
- allergic reactions (may present as hives, generalized urticaria, tightness of the chest, wheezing, shortness of breath, low blood pressure, for early symptoms see above)
- local reactions at the injection site such as bleeding under the skin, intense itching, swelling, burning sensation, temporary redness
- dizziness
- trouble falling asleep
- cough
- rash, skin reddening

Uncommon (may affect up to 1 in 100 people):

- taste disturbance
- flushing
- itching

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

To report any side effect(s):

The National Pharmacovigilance Centre (NPC):

SFDA Call Center: 19999

E-mail: npc.drug@sfd.gov.sa

Website: <https://ade.sfd.gov.sa>

5. How to store Jivi

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

Do not use this medicine after the expiry date which is stated on labels and cartons. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C - 8 °C). Do not freeze.

Keep the medicine in its original package in order to protect from light.

This medicine may be stored at room temperature (up to 25 °C) for up to 6 months when you keep it in its outer carton. If you store it at room temperature it expires after 6 months, or the expiry date if this is earlier.

The new expiry date must be noted on the outer carton when the medicine is removed from the refrigerator.

Do not refrigerate the solution after reconstitution. The reconstituted solution must be used within 3 hours.

Do not use this medicine if you notice any particles or the solution is cloudy.

This medicine is for single use only. Any unused solution must be discarded.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist or physician 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 Jivi contains

The **active** substance is PEGylated B-domain deleted recombinant human coagulation factor VIII (damoctocog alfa pegol). Each vial of Jivi contains nominally 500 or 1000 or 2000 IU damoctocog alfa pegol. The **other** ingredients are sucrose, histidine, glycine, sodium chloride, calcium chloride dihydrate, polysorbate 80, acetic acid glacial and water for injections.

What Jivi looks like and contents of the pack

Jivi is provided as a powder and solvent for solution for injection. The powder is dry, and white to slightly yellow. The solvent is a clear liquid. After reconstitution the solution is clear.

Each pack of Jivi contains

- a glass vial of powder
- a pre-filled syringe of solvent
- a separate plunger rod
- a vial adapter
- a venipuncture set

Manufactured by:

Bayer HealthCare LLC
Berkeley, USA.


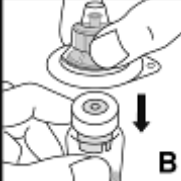



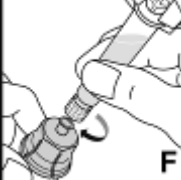
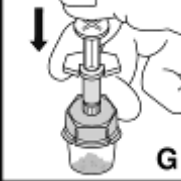
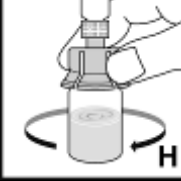
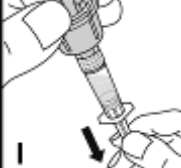
Final release by:


Bayer AG
51368 Leverkusen, Germany

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Detailed instructions for reconstitution and administration of Jivi

You will need alcohol swabs, gauze pads, plasters and tourniquet. These items are not included in the Jivi package.

1. Wash your hands thoroughly using soap and warm water.	
2. Hold an unopened vial and also a syringe in your hands to warm it to a comfortable temperature (do not exceed 37 °C).	
3. Remove the protective cap from the vial (A). Wipe the rubber stopper on the vial with an alcohol swab and allow the stopper to air dry before use.	
4. Place the powder vial on a firm, non-slip surface. Peel off the paper cover on the plastic housing of the vial adapter. Do not remove the adapter from the plastic housing. Holding the adapter housing, place over the product vial and firmly press down (B). The adapter will snap over the vial cap. Do not remove the adapter housing at this point.	
5. Hold the pre-filled syringe of solvent upright. Grasp the plunger rod as per the diagram and attach the rod by turning it firmly clockwise into the threaded stopper (C).	
6. Holding the syringe by the barrel, snap the syringe cap off the tip (D). Do not touch the syringe tip with your hand or any surface. Set the syringe aside for further use.	
7. Now remove and discard the adapter housing (E).	
8. Attach the pre-filled syringe to the threaded vial adapter by turning clockwise (F).	
9. Inject the solvent by slowly pushing down on the plunger rod (G).	
10. Swirl vial gently until all material is dissolved (H). Do not shake vial. Be sure that the powder is completely dissolved. Look to check there are no particles or discoloration before you use the solution. Do not use solutions containing visible particles or that are cloudy.	
11. Hold the vial on end above the vial adapter and syringe (I). Fill the syringe by drawing the plunger out slowly and smoothly. Ensure that the full content of the vial is drawn into the syringe. Hold the syringe upright and push the plunger until no air is left in the syringe.	

12. Apply a tourniquet to your arm.	
13. Determine the point of injection and clean the skin.	
14. Puncture the vein and secure the venipuncture set with a plaster.	
15. Holding the vial adapter in place, remove the syringe from the vial adapter (the adapter should remain attached to the vial). Attach the syringe to the venipuncture set (J). Ensure that no blood enters the syringe	
16. Remove tourniquet.	
17. Inject the solution into a vein over 2 to 5 minutes, keeping an eye on the position of the needle. The speed of injection should be based on your comfort, but should not be faster than 2.5 mL per minute.	
18. If a further dose is needed, use a new syringe with product reconstituted as described above.	
19. If no further dose is required, remove the venipuncture set and syringe. Hold a pad firmly over the injection site on your outstretched arm for about 2 minutes. Finally, apply a small pressure dressing to the injection site and consider if a plaster is necessary.	
20. It is recommended that every time you use Jivi, you note down the name and batch number of the product.	
21. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist or physician how to throw away medicines you no longer use. These measures will help protect the environment	