

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using JIVI®?

JIVI® contains the active ingredient PEGylated B-domain deleted recombinant human Factor VIII (damoctocog alfa pegol), produced by recombinant DNA technology. JIVI® is used for treatment and prevention of bleeding in previously treated adults and adolescents (from 12 years of age) with haemophilia A (congenital Factor VIII deficiency).

For more information, see Section [1. Why am I using JIVI®?](#) in the full CMI.

2. What should I know before I use JIVI®?

Do not use if you have ever had an allergic reaction to damoctocog alfa pegol, any other proteins that are of mouse or hamster origin, or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use JIVI®?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with JIVI® and affect how it works. Tell your doctor if you are taking any other medicines, including vitamins or supplements that you buy without prescription from your pharmacy, supermarket or health food shop.

For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use JIVI®?

- The dose of JIVI® is based on the severity of your clinical condition, your body weight, and the extent of bleeding. Your doctor or nurse will decide how much to inject.
- JIVI® will be given directly into your vein (intravenously) under the supervision of a doctor or a nurse. Once you have been trained, you should be able to inject this medicine at home, by yourself or with the help of a caregiver.

More instructions can be found in Section [4. How do I use JIVI®?](#) in the full CMI.

5. What should I know while using JIVI®?

Things you should do	<ul style="list-style-type: none"> • Remind any doctor, dentist, pharmacist or nurse you visit that you are using JIVI®. • Seek immediate medical attention if bleeding is not controlled after using JIVI®. • Tell your doctor if you have previously had an allergic reaction or hypersensitivity reaction to other Factor VIII products. • Seek immediate medical attention if you experience hypersensitivity or an allergic reaction.
Things you should not do	<ul style="list-style-type: none"> • Do not attempt to self-infuse unless you have been trained to self-administer. Always let your doctor or nurse do this.
Driving or using machines	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools until you know how JIVI® affects you.
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none"> • Store JIVI® under refrigeration at 2-8°C in the original container to protect from light. Do not freeze.

For more information, see Section [5. What should I know while using JIVI®?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. You may experience side effects while taking JIVI®, most of them are minor and temporary. You should call your doctor if you experience hypersensitivity or allergic reactions. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

JIVI[®] (Gee-v)

Active ingredient(s): damoctocog alfa pegol

Consumer Medicine Information (CMI)

This leaflet provides important information about using JIVI[®]. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using JIVI[®].**

Where to find information in this leaflet:

- [1. Why am I using JIVI[®]?](#)
- [2. What should I know before I use JIVI[®]?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use JIVI[®]?](#)
- [5. What should I know while using JIVI[®]?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using JIVI[®]?

JIVI[®] contains the active ingredient PEGylated B-domain deleted recombinant human Factor VIII (**damoctocog alfa pegol**), produced by recombinant DNA technology. Factor VIII is a protein naturally found in the blood that helps it to clot. Patients with haemophilia A lack sufficient factor VIII to control bleeding. JIVI[®] will help to treat and prevent bleeding episodes as well as prevent or reduce the frequency of bleeding episodes, occurring either spontaneously or due to injury, and bleeding during emergency and surgical procedures, by temporarily providing additional Factor VIII.

Jivi does not contain von Willebrand factor and therefore is not suitable for patients' requiring treatment of von Willebrand's disease.

JIVI[®] is used for treatment and prevention of bleeding in previously treated adults and adolescents (from 12 years of age) with haemophilia A (congenital Factor VIII deficiency).

2. What should I know before I use JIVI[®]?

Warnings

JIVI[®] is not for use in children less than 12 years of age.

Do not use JIVI[®] if:

- you are allergic to damoctocog alfa pegol, or any of the ingredients listed at the end of this leaflet.
- you are allergic to mouse or hamster proteins.
- you experience hypersensitivity or allergic reactions (which may include shortness of breath, wheezing or

difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching, or hives on the skin).

Check with your doctor if you:

- have previously had an allergic or hypersensitivity reaction to other Factor VIII products
- if you have heart disease or are at risk of heart disease.
- If you plan on taking any other medication while on treatment with JIVI[®].

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Contact your doctor for advice if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor if you have previously had an allergic or hypersensitivity reaction to other Factor VIII products.

Know the medicines you take. Keep a list of them to show to your doctor or pharmacist when you get a new medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect JIVI[®].

4. How do I use JIVI®?

Treatment with JIVI® will be started by a doctor who is experienced in the care of patients with haemophilia A. Once you have been trained, you should be able to inject this medicine at home, by yourself or with the help of a caregiver. Always use JIVI® 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.

How much to use

- The amount of JIVI® you need and the frequency with which it should be used depends on the clinical effect.
- Your doctor will decide how much JIVI® you use. The dose you receive will be based on the severity of your haemophilia A, your body weight, 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 and whether JIVI® is given to prevent or to treat bleeding.
- Follow the instructions provided and use JIVI® until your doctor tells you to stop. If you use the wrong amount, JIVI® may not work as well.

When to use JIVI®

- JIVI® can be used at any time of the day, before or after meals.

How to inject JIVI®

The instructions for reconstituting JIVI® with vial adapter and specific intravenous infusion instruction is provided at the end of this leaflet.

Please read the [‘How to Use Jivi’](#) section of this leaflet for step-by-step instructions.

If you forget to use JIVI®

Proceed with your next dose of JIVI® immediately and continue at regular intervals as advised by your doctor.

Do not take a double dose to make up for a forgotten dose.

If you use too much JIVI®

If you think that you have used too much JIVI®, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26** in Australia)
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using JIVI®?

Things you should do

- You should always follow the specific instructions given by your healthcare provider.

- If you are unsure of the procedures, please call your healthcare provider before using.
- If you have been trained to inject this medicine by yourself or with the help of a caregiver, handle JIVI® carefully and dispose of all materials, including any leftover reconstituted product.
- Remember that JIVI® is a single use product.
- Tests to measure the circulating levels of Factor VIII in your blood will be performed at intervals and are important to monitor the effectiveness of the treatment. Your doctor will decide when and how often to do this.

Call your doctor straight away if:

- The bleeding is not controlled after using JIVI®.
- You do not feel well while you are using JIVI®.

Remind any doctor, dentist or pharmacist you visit that you are using JIVI®.

Things you should not do

- Do not attempt to self-infuse and self-administer unless you have been trained to do so by your healthcare provider.
- Do not stop using JIVI® without consulting your doctor.
- Do not mix JIVI® with other infusion solutions.
- Do not use any component for administration if it is opened or damaged.
- Do not use JIVI® if you notice any discoloration or any particulates or turbidity (cloudiness) in the solution, after it has been mixed.
- Do not put the solution back into the fridge after it is mixed.
- Do not use JIVI® if it has passed its expiry date.

Inhibitors

- Treatment with Factor VIII product such as JIVI® may sometimes lead to the formation of antibodies (inhibitors) against Factor VIII and reduce the effectiveness of the treatment. Your doctor may wish to carry out tests to monitor inhibitor development.

Driving or using machines

No effects on ability to drive or use any machines or tools has been observed. Be careful until you know how JIVI® affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Product as packaged for sale:

- **Keep JIVI® in the refrigerator (2°C - 8°C). DO NOT FREEZE.**
- Keep JIVI® in the carton together with the prefilled diluent syringe until it is time to use it.
- Within the expiry date indicated on the label, this medicine may be stored at ambient room

temperature (up to 25°C) for up to 6 months when kept in its outer carton.

- When stored at ambient conditions, this medicine expires at the end of this 6- month period or the expiration date on the product vial, whichever is earlier. The new expiry date must be noted on the outer carton.
- Do not return the product to the refrigerator after it has been stored at 25°C.

Product after reconstitution:

- Do not refrigerate the solution after the powder is mixed with the diluent. After it is mixed, the solution must be used within 3 hours.

Keep it where young children cannot reach it.

Discard JIVI® if it has passed its expiry date.

Follow the instructions in the carton on how to take care of your medicine properly.

Getting rid of any unwanted medicine

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over. Do not throw away any medicine via wastewater or household waste.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Injection-site reactions: <ul style="list-style-type: none">• Burning sensation• Itching• Swelling• Temporary redness• Rash/ skin reddening General effects: <ul style="list-style-type: none">• Headache• Fever• Dizziness• Trouble falling asleep• Cough• Taste disturbance• Flushing Stomach related: <ul style="list-style-type: none">• Stomach pain• Nausea/vomiting If any of the side effects gets serious, or if you notice any side	Speak to your doctor if you have any of these less serious side effects and they worry you. Speak to your doctor or pharmacist.

effects not listed in this leaflet

Serious side effects

Serious side effects	What to do
Signs of a rare severe sudden allergic reaction to the medicine may include: <ul style="list-style-type: none">• Tightness in the chest, general feeling of being unwell• Burning and stinging sensation at the application site• Itchy nettle-rash• Wheezing• Feeling sick or faint Vascular disorder: <ul style="list-style-type: none">• Reduced or low blood pressure (often shown by feeling dizzy when getting up quickly) Blood and lymphatic system disorders <ul style="list-style-type: none">• Factor VIII inhibition	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What JIVI® contains

Active ingredient (main ingredient)	damoctocog alfa pegol
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• sucrose• histidine• glycine• sodium chloride• calcium chlorise dihydrate• polysorbate 80

Potential allergens	not applicable
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Do not take this medicine if you are allergic to any of these ingredients.

What JIVI® looks like

JIVI® is white to slightly yellow powder for reconstitution with water as diluent for intravenous (IV) injection.

After reconstitution the solution is clear. Medical devices for reconstitution and administration are provided with each package of JIVI®.

Each pack of JIVI® contains a vial and a pre-filled syringe with a separate plunger rod, a venipuncture set (for injection into a vein).

JIVI® 250 IU - Aust R 384590, JIVI® 500 IU - Aust R 384592, JIVI® 1000 IU - Aust R 384594, JIVI® 2000 IU - Aust R 384593, JIVI® 3000 IU - Aust R 384591.

Who distributes JIVI®

Bayer Australia Limited

ABN 22 000 138 714

875 Pacific Highway, Pymble NSW 2073

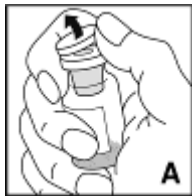
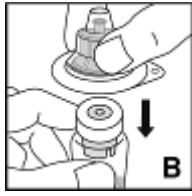
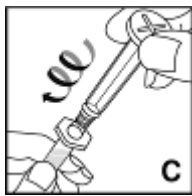
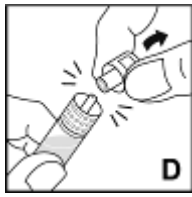
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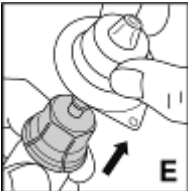
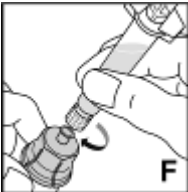
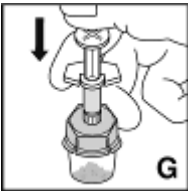
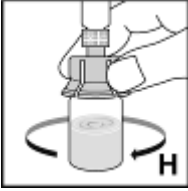
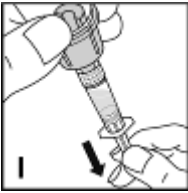
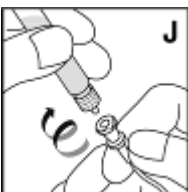
This leaflet was prepared on 27 March 2023.

HOW TO USE JIVI®

Reconstitution and administration:

- You will need alcohol swabs, gauze pads, plasters and tourniquet. These items are not included with your JIVI® pack.
- The reconstituted product must be filtered prior to administration to remove potential particulate matter in the solution. Filtering is achieved by using the vial adapter.
- Place needles in a sharps container after single-use. Discard all equipment, including any reconstituted JIVI® product, in accordance with biohazard procedures.

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 water for injections 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