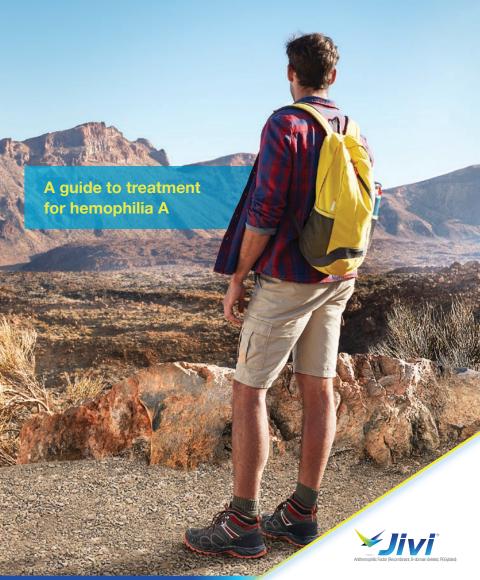


# GETTING TO KNOW JIVI



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### **WELCOME TO JIVI**

This booklet was designed to help you learn more about Jivi and better understand this treatment. It is meant to be a helpful guide that complements the information provided by your healthcare professional.



# Here are a few of the topics discussed in this booklet:

- A general overview of Jivi
- Dosing information and available vial sizes
- Instructions on how to properly store Jivi
- A list of possible side effects and other safety information
- Helpful resources

There is also a notes section at the end to help you keep track of information from your healthcare professional or any questions you may have about your treatment.

Remember that your healthcare professional is your best source of information should you have any questions about hemophilia A and your treatment with Jivi



### WHY HAVE I BEEN PRESCRIBED JIVI®?

Jivi is for the treatment of hemophilia A in previously treated patients (PTPs) 12 years of age and older.

Jivi can be used to:

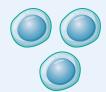
- prevent bleeding before it happens
- stop a bleeding episode that has already begun

Jivi is not for use in children <12 years of age and in previously untreated patients.

Jivi is not for the treatment of von Willebrand disease.

# **HOW DOES JIVI WORK?**

In people who don't have hemophilia A, a protein called Factor VIII is produced naturally by the body to help the blood form clots and stop bleeding.



People with hemophilia A do not have enough Factor VIII in their body. When they are injured, they may bleed internally, which can lead to damage in muscles and joints.

Jivi (Antihemophilic Factor [Recombinant, B-domain deleted, PEGylated]) contains clotting Factor VIII and is given directly into the blood through an injection in a vein.

By raising the level of Factor VIII in the blood, Jivi can help prevent bleeding before it happens or stop a bleeding episode that has already begun.

Jivi has a component called polyethylene glycol (PEG) that helps it to remain active in the body for longer (have a longer half-life).



### WHO SHOULDN'T TAKE JIVI®?

Do not use Jivi if:

- you are allergic (hypersensitive) to Jivi, or to any of the other ingredients of Jivi\*
- you have had allergic reactions to mouse or hamster protein

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Jivi.

# Tell your healthcare professional about:



 Any health conditions or problems you may have, including if you are allergic to mouse or hamster protein.



 Whether you have been told you have heart disease or are at risk for heart disease.



 All the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

There are no known interactions with Jivi and other medications. However, please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

### WHAT IS THE USUAL DOSE OF JIVI?



# **Prevention of bleeding (prophylaxis)**

The recommended initial dose for Jivi is:

30-40 IU

of Jivi for every kilogram of body weight, given twice weekly

Based on bleeding episodes, the dose can be adjusted to 45–60 IU/kg every 5 days. A regimen may be further individually adjusted to more or less frequent dosing.

Jivi is given by injection into the bloodstream (intravenously).

Your doctor will individualize your Jivi regimen to meet your specific needs. To get the most out of your treatment, be sure to administer Jivi at the dose and frequency prescribed by your doctor.





<sup>\*</sup> Non-medicinal ingredients: calcium chloride, histidine, glycine, polysorbate 80, sodium chloride, sucrose.

# WHAT IS THE USUAL DOSE OF JIVI®?



# Treatment of bleeding

Your doctor will calculate how much Jivi you should use and how often you should use it based on many factors including:

- Your weight
- The severity of your hemophilia
- Where the bleed is and how serious it is
- Whether you have inhibitors and the level of inhibitors in vour blood
- The level of Factor VIII that is needed

Your doctor will calculate the dose of Jivi and how frequently you should use it to get the necessary level of Factor VIII activity in your blood. Your doctor should always adjust the amount of Jivi to be administered and the frequency of administration according to your individual needs. Under certain circumstances larger amounts than those calculated may be required, especially for the initial dose.

Jivi is given by injection into the bloodstream (intravenously).

# Laboratory test

After treatment, it is strongly recommended that appropriate laboratory tests be performed on your plasma at suitable intervals to ensure that adequate Factor VIII levels have been reached and are maintained. For major surgery in particular, close monitoring of the treatment by means of coagulation analysis must be carried out.

# If bleeding is not controlled

If the Factor VIII level in your plasma fails to reach expected levels, or if bleeding is not controlled after an adequate dose, you may have developed Factor VIII inhibitors. This must be checked by an experienced doctor.

If you feel the effect of Jivi is too strong or too weak, talk to your doctor.

#### **Patients with inhibitors**

If you have been told by your doctor that you have developed Factor VIII inhibitors, you may need to use a larger amount of Jivi to control bleeding.

Do not increase the dose of Jivi you use to control your bleeding without consulting your doctor.

#### **Duration of treatment**

Your doctor will tell you how often and at what intervals Jivi is to be administered.

Usually, replacement therapy with Jivi is a life-time treatment.

# WHAT IF I MISS A DOSE OR OVERDOSE?

#### Missed dose

If you miss a dose of Jivi proceed with your next dose immediately and continue at regular intervals, as advised by your doctor.



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

# **Overdose**

No symptoms of overdose with recombinant coagulation Factor VIII have been reported.

If you think you have taken too much Jivi, contact your healthcare professional, hospital emergency department or regional Poison **Control Centre immediately –** even if there are no symptoms



### WHAT VIAL SIZES ARE AVAILABLE FOR JIVI®?

Jivi is available in the following single-use vial sizes and is prepared with 2.5 mL of sterile water for injection:



# What comes in each package?

Each Jivi package contains:

- Single-use vial with powder
- Prefilled syringe containing diluent (sterile water for injection)
- Vial adapter
- Administration set



# **HOW SHOULD I STORE JIVI?**



# 2-8°C under refrigeration

Jivi should be stored in a refrigerator, between 2°C to 8°C. Keep the vial and the prefilled syringe in the outer carton in order to protect them from light.



Jivi can be stored in its outer carton at room temperature up to 25°C for 6 months or up to 30°C for 3 months. Once the product is removed from refrigeration, it cannot be returned to the refrigerator.

Up to 25°C for 6 MONTHS when kept in outer carton to protect from light



#### Do not freeze

**Do not** use beyond the expiration date on the labels and cartons

If you store Jivi outside of your refrigerator, please add the date removed from refrigeration and note a new expiry date on the carton and vial. The new expiry date should be 6 months (25°C) or 3 months (30°C) from the date product is removed from the refrigerator, or the previously stamped expiry date, whichever is shorter.

Use immediately (within 3 hours) after reconstitution

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

Keep Jivi out of reach and sight of children



# WHAT ARE THE POSSIBLE SIDE EFFECTS OF JIVI°?

Like all medicines, Jivi may cause side effects – although not everybody gets them. Most side effects from using Jivi are mild to moderate.

# Very common May affect 10% or more of people

Headache

# Common May affect 1% to less than 10% of people

- Hypersensitivity reactions, including tightness of the chest/general feeling of being unwell, dizziness and nausea, and mildly reduced blood pressure, which may make you feel faint upon standing. Severe allergic reactions or anaphylactic shock (an uncommon, severe allergic reaction affecting blood pressure and breathing) have not been reported during clinical trials with Jivi.
- Stomach pain/discomfort
- Vomiting
- Fever
- Cough
- Local reactions where you injected the medication
- Dizziness
- Trouble falling asleep
- Rash/itchy rash

# WHAT ARE THE POSSIBLE SIDE EFFECTS OF JIVI?

# Uncommon May affect 0.1% to less than 1% of people

- Dysgeusia (odd taste)
- Hives
- Flushing (redness of the face)

These are not all the possible side effects that you may feel when taking Jivi. Contact your healthcare professional if you experience any side effects not listed here.



# Serious side effects and what to do about them

If you experience hypersensitivity reactions including tightness of the chest as well as a general feeling of being unwell, dizziness and nausea with mildly reduced blood pressure, which may make you feel faint upon standing, stop taking Jivi and get immediate medical help.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional



# IS THERE OTHER IMPORTANT SAFETY INFORMATION I SHOULD KNOW ABOUT?

# Allergic reactions to JIVI° have occurred

If you experience tightness in the chest, feel dizzy, sick or faint, or experience dizziness upon standing, you may be experiencing a rare severe sudden allergic reaction (a so-called anaphylactic reaction) to Jivi. If this occurs, stop administration of the product immediately and seek medical advice.

#### **Factor VIII Inhibitors**

Your doctor may carry out tests to ensure that your current dose of Jivi provides adequate Factor VIII levels.

If your bleeding is not being controlled with your usual dose of Jivi, consult your doctor immediately. Your body may have formed molecules known as Factor VIII inhibitors and your doctor may carry out tests to confirm this.

Antibodies to PEG may block the activity of Jivi, making it less effective to prevent and control bleeding. Your doctor may switch you to your previous Factor VIII treatment without delay.

Factor VIII inhibitors are antibodies in the blood and are a natural part of the body's defense system. Your doctor may consider other treatment options.

# IS THERE OTHER IMPORTANT SAFETY INFORMATION I SHOULD KNOW ABOUT?

# **Surgical devices**

When frequent injections are required, your healthcare professional may propose to have a device (called a catheter) surgically placed under the skin to facilitate access to the bloodstream. This device may result in an infection. Inform your healthcare provider if you have a catheter-related infection.



Tell your healthcare provider if you have been told you have heart disease or are at risk for heart disease.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.



# **NOTES**

Use this space to keep track of notes regarding your treatment or any questions you may have for your healthcare provider.

# **NOTES**

Use this space to keep track of notes regarding your treatment or any questions you may have for your healthcare provider.
CONTACT DETAILS
Healthcare provider name:
Clinic name:
Address:
Phone: Fax:
Email:



#### JIVI® SUPPORT

#### The Jivi online resource centre



### A JIVI PATIENT HUB WILL BE AVAILABLE

The Jivi Patient Hub will be an online resource centre available for anyone who has been prescribed and is looking for more information.

# **JIVI SUPPORT**

# **KoKonnect**<sup>™</sup> Patient Support Program

KoKonnect<sup>™</sup> is a support program that aims to help people prescribed Jivi receive in-home treatment support.

KoKonnect<sup>™</sup> can:

- Provide you with instruction on how to reconstitute Jivi
- Connect you with nurses who can provide in-home infusions in certain situations
- Give you and your family information and support to help you learn how to perform infusions on your own

Ask your doctor if you're eligible to enroll in KoKonnect™.





### **Want more information on JIVI?**

Please refer to the package insert included with Jivi.

You can also speak with your healthcare professional or contact Bayer Medical Information at 1-800-265-7382 (7:30 am to 7:30 pm EST).

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