For your patients 12 years of age and older

Flexibility to Decrease Dosing Frequency with Jivi®

Starting with twice-weekly dosing, Jivi offers step-wise dosing based on bleeding episodes.*

What is Jivi?

Jivi, antihemophilic factor (recombinant), PEGylated-aucl, is an extended half-life recombinant Factor VIII concentrate with proven protection, safety and unique step-wise dosing.

Who is Jivi for?

Jivi is used to treat and control bleeding in previously treated adults, adolescents and children (7 years of age and older) with hemophilia A. Please see limitations of use below.

Step-wise dosing

For patients 12 years of age and older, Jivi offers the potential for fewer infusions with a twice-weekly starting dose and the potential to adjust to every 5 days and fine-tune based on bleeding episodes.[1]

8 out of 10 patients 12 years of age and older in PROTECT VIII reduced dosing frequency vs their pre-study prophylaxis regimen in the main study.†,‡,[2]

*Please see full **Jivi Prescribing Information** for complete dosing information.
†n=40/47 patients in the every-5-days and twice-weekly dosing arms for whom prior prophylaxis dosing records were available.[2]
‡PROTECT VIII was a multinational, prospective, single-arm study in adult and pediatric previously treated patients (PTPs) 12 to 65 years of age.[3]

INDICATION

- JIVI is a recombinant DNA-derived, Factor VIII concentrate indicated for use in previously treated adults and pediatric patients 7 years of age and older with hemophilia A (congenital Factor VIII deficiency) for:
  - On-demand treatment and control of bleeding episodes.
  - Perioperative management of bleeding.
  - Routine prophylaxis to reduce the frequency of bleeding episodes.
- Limitations of use
  JIVI is not indicated for use in:
  - Children <7 years of age due to a greater risk for hypersensitivity reactions and/or loss of efficacy.
  - Previously untreated patients (PUPs).
  - Treatment of von Willebrand disease.

SELECTED IMPORTANT SAFETY INFORMATION

- JIVI is contraindicated in patients who have a history of hypersensitivity reactions to the active substance, polyethylene glycol (PEG), mouse or hamster proteins, or other constituents of the product.

For additional important risk and use information, please see the full Prescribing Information.

Jivi®
antihemophilic factor (recombinant) PEGylated-aucl

Jivi® dosing frequency can be adjusted based on bleeding episodes

Start patients on a 2-times-per-week dosing regimen with Jivi. From there, you can adjust your patient's dosing up or down based on bleeding episodes.

		For patients ≥12 years
Start simply	**TWICE WEEKLY**	Recommended starting regimen for Jivi is twice weekly (30-40 IU/kg) for all prophylaxis patients.*,[3]
Adjust	**EVERY 5 DAYS**	Based on bleeding episodes, less frequent dosing of Jivi every 5 days (45-60 IU/kg) can be used.*,[3]
Fine-tune regimen	**UP OR DOWN**	From there, you have the flexibility to adjust your patient's dosing frequency up or down as needed, based on bleeding episodes.[3]

Click here to learn more about Jivi dosing.

*100% of patients in the every-5-days and twice-weekly dosing arms remained on the same dosing regimen for the duration of the main study.[3]

SELECTED IMPORTANT SAFETY INFORMATION

- Hypersensitivity reactions, including severe allergic reactions, have occurred with JIVI. Monitor patients for hypersensitivity symptoms. Early signs of hypersensitivity reactions, which can progress to anaphylaxis, may include chest or throat tightness, dizziness, mild hypotension and nausea. If hypersensitivity reactions occur, immediately discontinue administration and initiate appropriate treatment.
- JIVI may contain trace amounts of mouse and hamster proteins. Patients treated with this product may develop hypersensitivity to these non-human mammalian proteins.
- Hypersensitivity reactions may also be related to antibodies against polyethylene glycol (PEG).
- Neutralizing antibody (inhibitor) formation has occurred following administration of JIVI. Carefully monitor patients for development of Factor VIII inhibitors, using appropriate clinical observations and laboratory tests. If expected plasma Factor VIII activity levels are not attained or if bleeding is not controlled as expected with administered dose, suspect the presence of an inhibitor (neutralizing antibody).

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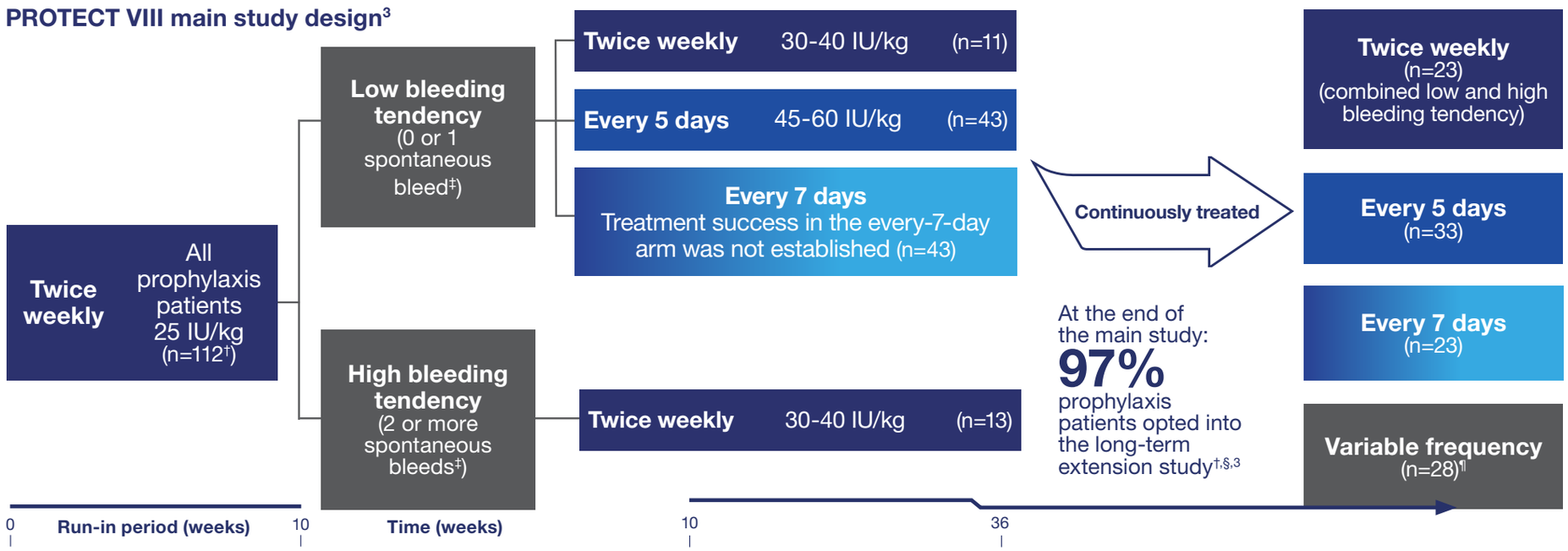
antihemophilic factor
(recombinant) PEGylated-aucl

PROTECT VIII main and extension studies*

The PROTECT VIII main and extension studies were designed to reflect real-world treatment in patients 12 years of age and older[1,4]

Patients completing the PROTECT VIII main study were invited to continue on to the extension study.[4] Patients on a prophylaxis regimen could continue their current regimen or switch to another dosing regimen on entry to the extension study and at any point during it.

PROTECT VIII main study design[3]



Long-term extension study design[4]

Click here to learn more about the PROTECT VIII main and extension studies.

*PROTECT VIII was a multinational, prospective, single-arm study in adult and pediatric previously treated patients (PTPs) 12 to 65 years of age.[3]
†112 patients entered prophylactic treatment arms; an additional 20 patients entered a control arm of on-demand treatment. Two patients in the prophylactic arms left the main study prematurely during the run-in period.[3]
‡Defined as joint or muscle bleeds and no identified trauma.[1,3]
§121 of 134 patients included in the main PROTECT VIII trial continued in the extension study, receiving either on-demand treatment (n=14) or prophylaxis (n=107).[4]
¶Patients who switched dosing frequency at least once after the first week of the extension study were analyzed in a separate variable-frequency group.[4]

SELECTED IMPORTANT SAFETY INFORMATION

- An immune response associated with IgM anti-PEG antibodies, manifested as symptoms of acute hypersensitivity and/or loss of drug effect, has occurred with JIVI® administration. In the clinical trials, the IgM anti-PEG antibodies disappeared within 4-6 weeks. No immunoglobulin class switching from IgM to IgG has been observed.
- A low post-infusion Factor VIII level, in absence of detectable Factor VIII inhibitors, may be due to loss of treatment effect related to high titers of anti-PEG IgM antibodies. In these cases, discontinue JIVI and switch patients to a different anti-hemophilic product.
- A reduced recovery of Factor VIII after start of JIVI treatment may be due to transient low titers of anti-PEG IgM antibodies. In these cases, increase the dose of JIVI until recovery of Factor VIII returns to expected levels.
- The most common (incidence ≥5%) adverse reactions in clinical trials in previously treated patients (PTPs) ≥7 years of age were headache, fever, cough, and abdominal pain.

For additional important risk and use information, please see the full Prescribing Information.

Jivi®
antihemophilic factor (recombinant) PEGylated-aucl

Indication and important safety information for Jivi®

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  - On-demand treatment and control of bleeding episodes.
  - Perioperative management of bleeding.
  - Routine prophylaxis to reduce the frequency of bleeding episodes.
- Limitations of use
  JIVI is not indicated for use in:
  - Children <7 years of age due to a greater risk for hypersensitivity reactions and/or loss of efficacy.
  - Previously untreated patients (PUPs).
  - Treatment of von Willebrand disease.

IMPORTANT SAFETY INFORMATION

- JIVI is contraindicated in patients who have a history of hypersensitivity reactions to the active substance, polyethylene glycol (PEG), mouse or hamster proteins, or other constituents of the product.
- Hypersensitivity reactions, including severe allergic reactions, have occurred with JIVI. Monitor patients for hypersensitivity symptoms. Early signs of hypersensitivity reactions, which can progress to anaphylaxis, may include chest or throat tightness, dizziness, mild hypotension and nausea. If hypersensitivity reactions occur, immediately discontinue administration and initiate appropriate treatment.
- JIVI may contain trace amounts of mouse and hamster proteins. Patients treated with this product may develop hypersensitivity to these non-human mammalian proteins.
- Hypersensitivity reactions may also be related to antibodies against polyethylene glycol (PEG).
- Neutralizing antibody (inhibitor) formation has occurred following administration of JIVI. Carefully monitor patients for development of Factor VIII inhibitors, using appropriate clinical observations and laboratory tests. If expected plasma Factor VIII activity levels are not attained or if bleeding is not controlled as expected with administered dose, suspect the presence of an inhibitor (neutralizing antibody).
- An immune response associated with IgM anti-PEG antibodies, manifested as symptoms of acute hypersensitivity and/or loss of drug effect, has occurred with JIVI administration. In the clinical trials, the IgM anti-PEG antibodies disappeared within 4-6 weeks. No immunoglobulin class switching from IgM to IgG has been observed.
- A low post-infusion Factor VIII level, in absence of detectable Factor VIII inhibitors, may be due to loss of treatment effect related to high titers of anti-PEG IgM antibodies. In these cases, discontinue JIVI and switch patients to a different anti-hemophilic product.
- A reduced recovery of Factor VIII after start of JIVI treatment may be due to transient low titers of anti-PEG IgM antibodies. In these cases, increase the dose of JIVI until recovery of Factor VIII returns to expected levels.
- The most common (incidence ≥5%) adverse reactions in clinical trials in previously treated patients (PTPs) ≥7 years of age were headache, fever, cough, and abdominal pain.

References: 1. Reding MT et al. J Thromb Haemost 2017;15:411-419. **2.** Kerlin BA et al. Poster P153. Presented at the 4th Biennial Summit of the Thrombosis & Haemostasis Societies of North America. March 8-10, 2018, San Diego, California. **3.** Jivi Prescribing Information. May 2025. Bayer. **4.** Reding M, et al. Haemophilia. 2021; 10.1111/hae.14297.

For additional important risk and use information, please see the full Prescribing Information.
You are encouraged to report negative side effects or quality complaints of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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