

Don't miss the opportunity to learn more about Jivi, an extended half-life recombinant factor VIII therapy!

Jivi[®]
antihemophilic factor
(recombinant) PEGylated-aucl



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. [CONTINUE READING BELOW](#)

Jivi[®]: The extended half-life recombinant factor VIII with proven protection and unique step-wise dosing.

Please see important details below about how to learn more.



Presentation Overview:	This presentation includes key information on Jivi, including: <ul style="list-style-type: none"> • Hemophilia A Treatment Landscape • Jivi Clinical Profile • Treatment Cost Considerations • Bayer Commitment • Summary
When:	Date: [place holder for date] Time: 6:00 p.m. to 7:00 p.m. PST
Registration Link:	[Placeholder for CPhA webinar registration link]
Featured Speaker(s):	[speaker name(s) place holder] [Title(s) placeholder]

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INDICATIONS

- Jivi antihemophilic factor (recombinant), PEGylated-aucl, is a recombinant DNA-derived, Factor VIII concentrate indicated for use in previously treated adults and adolescents (12 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 less than 12 years of age due to a greater risk for hypersensitivity reactions.
 - Jivi is not indicated for use in previously untreated patients (PUPs).

INDICATIONS (cont.)

- o Jivi is not indicated for the 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 can occur following administration of Jivi. Carefully monitor patients for the 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).
- A clinical immune response associated with IgM anti-PEG antibodies, manifested as symptoms of acute hypersensitivity and/or loss of drug effect, has been observed primarily in patients < 6 years of age. The symptoms of the clinical immune response were transient. Anti-PEG IgM titers decreased over time to undetectable levels. No immunoglobulin class switching was observed.
- In case of clinical suspicion of loss of drug effect, conduct testing for Factor VIII inhibitors and Factor VIII recovery. A low post-infusion Factor VIII level in the absence of detectable Factor VIII inhibitors indicates that loss of drug effect is likely due to anti PEG antibodies. Discontinue Jivi and switch patients to a previously effective Factor VIII product.
- The most frequently (≥5%) reported adverse reactions in clinical trials in previously treated patients (PTPs) ≥12 years of age were headache, cough, nausea, and fever.

For additional important risk and use information, please see [full Prescribing Information](#)

You are encouraged to report side effects or quality complaints of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.