

Prescribing Information

Please use the links below to view full Prescribing Information for XYNTHA, XYNTHA SOLOFUSE, and BeneFIX.



Antihemophilic Factor (Recombinant)



Antihemophilic Factor (Recombinant)

[Download PDF of Prescribing Information for XYNTHA](#)

[Download PDF of Prescribing Information for XYNTHA SOLOFUSE](#)



Coagulation Factor IX (Recombinant)

Room Temperature Storage

[Download PDF of Prescribing Information for BeneFIX](#)

What is XYNTHA?

XYNTHA[®] Antihemophilic Factor (Recombinant) is indicated in adults and children for the control and prevention of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency or classic hemophilia) and for the prevention of bleeding during surgery in patients with hemophilia A.

XYNTHA does not contain von Willebrand factor and, therefore, is not indicated for von Willebrand's disease.

Important Safety Information for XYNTHA

- Call your healthcare provider or go to the emergency department right away if you have any of the following symptoms because these may be signs of a serious allergic reaction: wheezing, difficulty breathing, chest tightness, turning blue (look at lips and gums), fast heartbeat, swelling of the face, faintness, rash, low blood pressure, or hives. XYNTHA contains trace amounts of hamster protein. You may develop an allergic reaction to these proteins. Tell your healthcare provider if you have had an allergic reaction to hamster protein

- Call your healthcare provider right away if bleeding is not controlled after using XYNTHA; this may be a sign of an inhibitor, an antibody that may stop XYNTHA from working properly. Your healthcare provider may need to take blood tests to monitor for inhibitors
- Across all clinical studies, the most common side effects (10% or more) with XYNTHA in adult and pediatric previously treated patients (PTPs) were headache (26% of subjects), joint pain (25%), fever (21%), and cough (11%). Other side effects reported in 5% or more of patients were: diarrhea, vomiting, weakness, and nausea
- XYNTHA is an injectable medicine administered by intravenous (IV) infusion. You may experience local irritation when infusing XYNTHA after reconstitution in XYNTHA[®] SOLOFUSE[®].

Please see full [Prescribing Information](#) for XYNTHA and XYNTHA SOLOFUSE.

What Is BeneFIX?

BeneFIX[®] Coagulation Factor IX (Recombinant) is an injectable medicine that is used to help control and prevent bleeding in people with hemophilia B. Hemophilia B is also called congenital factor IX deficiency or Christmas disease.

BeneFIX is **NOT** used to treat hemophilia A.

Important Safety Information for BeneFIX

- BeneFIX is contraindicated in patients who have manifested life-threatening, immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including hamster protein.
- Call your health care provider right away if your bleeding is not controlled after using BeneFIX.
- Allergic reactions may occur with BeneFIX. Call your health care provider or get emergency treatment right away if you have any of the following symptoms: wheezing, difficulty breathing, chest tightness, your lips and gums turning blue, fast heartbeat, facial swelling, faintness, rash or hives.
- Your body can make antibodies, called "inhibitors," which may stop BeneFIX from working properly.
- If you have risk factors for developing blood clots, such as a venous catheter through which BeneFIX is given by continuous infusion, BeneFIX may increase the risk of abnormal blood clots. The safety and efficacy of BeneFIX administration by continuous infusion have not been established.
- Some common side effects of BeneFIX are nausea, injection site reaction, injection site pain, headache, dizziness and rash.

Please see full [Prescribing Information](#) for BeneFIX