

## PART III: CONSUMER INFORMATION

### **BeneFIX<sup>®</sup>** **Coagulation Factor IX (Recombinant)**

**This leaflet is part III of a three-part "Product Monograph and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about BeneFIX. Contact your doctor or hemophilia treatment centre if you have any questions about the drug.**

#### **ABOUT THIS MEDICATION**

##### **What the medication is used for:**

- The control and treatment of bleeding and the prevention of bleeding in people with hemophilia B.
- BeneFIX has been approved for use in hemophilia B for adults and children.
- Ask your doctor if you have any questions about why BeneFIX has been prescribed for you.

##### **What it does:**

- Factor IX is a protein produced naturally in the body. It helps the blood form clots to stop bleeding.
- People with hemophilia B (Christmas disease) are deficient in coagulation factor IX.
- When the body does not make enough factor IX, and you become injured, your blood will not form clots as it should, and you may bleed into and damage your muscles and joints.
- Injections of factor IX are used to treat hemophilia B.
- BeneFIX is created using recombinant technology that allows it to be made without human blood or plasma products, making it naturally free of blood borne pathogens.

##### **When it should not be used:**

- Do not use BeneFIX for the treatment of other coagulation factor deficiencies (e.g., factors II, VII and X), for the treatment of hemophilia A, in patients with inhibitors to factor VIII, for the reversal of coumarin-induced anticoagulation, nor for the treatment of bleeding due to low levels of liver-dependent coagulation factors.
- Do not use BeneFIX if you are allergic to hamster proteins or any of the nonmedicinal ingredients listed below.
- Do not use BeneFIX after the expiry date (printed on the bottle). If you take this medicine after the expiry date has passed, it may not work well.
- Do not use BeneFIX if the packaging is torn or shows signs of tampering.

If you are not sure whether you should use BeneFIX, talk to your doctor.

##### **What the medicinal ingredient is:**

- Recombinant coagulation Factor IX (Nonacog alfa)

##### **What the important nonmedicinal ingredients are:**

- Glycine
- Sucrose
- Histidine
- Polysorbate 80
- Water for injection

### **What dosage forms it comes in:**

BeneFIX comes as a white powder in a glass vial, nominally containing 250, 500 or 1000 IU per vial. The actual amount of Factor IX is stated on the label of each bottle. BeneFIX must be reconstituted (dissolved) with the diluent vial and the product contains approximately: 50, 100, and 100 IU/mL, respectively.



## **WARNINGS AND PRECAUTIONS**

### **Serious Warnings and Precautions**

**STOP taking BeneFIX and contact your doctor immediately if**

- **You experience allergic reactions such as skin rash, itching, chest tightness, wheezing, dizziness, hives, faintness, rapid heartbeat, shortness of breath, and/or a swollen face. Severe allergic reactions to BeneFIX and other Factor IX products have been reported.**

**Contact your doctor immediately if**

- **Your bleeding does not stop as expected**

**BEFORE you use BeneFIX talk to your doctor or hemophilia treatment centre if you:**

- Are pregnant or planning to become pregnant
- Are breast feeding or planning to breast feed
- Are allergic or hypersensitive to latex rubber
- Are at risk of developing blood clots
- Have liver disease
- Have recently had surgery or are planning to have surgery, including dental surgery

## **INTERACTIONS WITH THIS MEDICATION**

**Drugs that may interact with BeneFIX include:**

- There are no known interactions of BeneFIX with other medications.

- Tell your doctor or pharmacist if you are taking any other medicines, including any you buy without a prescription, including natural health products.

## **PROPER USE OF THIS MEDICATION**

### **Usual dose:**

- Your doctor will decide the dose of BeneFIX you will receive.
- BeneFIX is injected directly into the bloodstream.
- The dose, duration and frequency of infusion will depend on your individual needs for replacement factor IX and may be influenced by your age, weight, activity level and severity of bleed.
- Your doctor may periodically need to check laboratory blood test results following infusion to be sure that blood level of factor IX is high enough to allow satisfactory blood clotting.
- If you have been using plasma-derived factor IX, the dose of BeneFIX may differ from the dose of plasma-derived factor IX.
- Do not lower the dose of BeneFIX without checking with your doctor, unless you are having an allergic reaction.

### **Overdose:**

- No symptoms of overdose are known.

### **Missed Dose:**

- If you miss a dose of this medicine, check with your doctor as soon as possible for instructions.

### **Preparation and Administration:**

The procedures below are provided as general guidelines for the preparation (reconstitution) and administration of BeneFIX. Patients should follow the specific preparation and administration procedures provided by their physicians.

### **Preparation**

- Always wash your hands before performing the following procedures.



- Allow the vials of lyophilized BeneFIX and diluent to reach room temperature.



- Remove the plastic, flip-top caps from the BeneFIX vial and the diluent vial to expose the central portions of the rubber stoppers.



- Wipe the tops of both vials with the alcohol swab provided, or use another antiseptic solution, and allow to dry.



- Remove the protective cover from the short end of the sterile double-ended needle and insert the short end into the diluent vial at the center of the stopper.



- Remove the protective cover from the long end of the needle.



- Invert the solvent vial and, to minimize leakage, quickly insert the long end of the needle through the center of the stopper of the upright BeneFIX vial.
- *Note: Point the double-ended needle toward the wall of the BeneFIX vial to prevent excessive foaming.*



- The vacuum will draw the diluent into the BeneFIX vial.



- Once the transfer is complete, remove the long end of the needle from the BeneFIX vial and properly discard the needle with the diluent vial.

- *Note: If the diluent does not transfer completely into the BeneFIX vial, DO NOT USE the contents of the vial. Note that it is acceptable for a small amount of fluid to remain in the diluent vial after transfer.*



- Gently rotate the vial to dissolve the powder.



- BeneFIX should be inspected visually for particles that have not dissolved and discoloration prior to administration, whenever solution and container permit. Reconstituted BeneFIX should appear *clear and colorless*.



### **Administration (Intravenous Injection)**

- BeneFIX is administered by intravenous (IV) infusion after reconstitution with Sterile Water for Injection (USP).
- BeneFIX Coagulation Factor IX (Recombinant), should be administered using a single sterile disposable plastic syringe. In addition, the solution should be withdrawn from the vial using the sterile filter spike.



- Using aseptic technique, attach the sterile filter spike to the sterile disposable syringe.
- *Note: Do NOT inject air into the BeneFIX vial. This may cause partial loss of product.*



- Insert the filter spike end into the stopper of the BeneFIX vial.



- Invert the vial and withdraw the reconstituted solution into the syringe.



- Remove and discard the filter spike.
- *Note: If you use more than one vial of BeneFIX, the contents of multiple vials may be drawn into the same syringe through a separate, unused filter spike.*



- Attach the syringe to the Luer end of the infusion set tubing and perform venipuncture as instructed by your physician.



- After preparation (reconstitution), BeneFIX should be injected intravenously over several minutes.
- The rate of administration should be determined by the patient's comfort level.
- Unused solution, empty vials, and used needles and syringes might hurt others if not handled properly. Dispose of these in an appropriate container provided by your physician.

- *Note: Clumping (agglutination) of red blood cells in the tubing/syringe has been reported with the administration of BeneFIX. No adverse events have been reported in association with this observation. To minimize the possibility of agglutination, it is important to limit the amount of blood entering the tubing. Blood should not enter the syringe. If red blood cell agglutination is observed in the tubing or syringe, discard all material (tubing, syringe and BeneFIX solution) and resume administration with a new package.*



## **SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

- During your treatment with BeneFIX, your blood will be checked for inhibitors to factor IX activity. Inhibitors are antibodies against Factor IX, which are made by your immune system. The inhibitors stop the factor IX from working as well as it used to.

**Tell your doctor immediately if you are using increasing amounts of BeneFIX in order to control a bleed.**

- Injection of any medicine intravenously may have side effects. Often they are not serious but sometimes they can be. You may need medical treatment if you experience some of the side effects in the table below.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect	STOP taking BeneFIX and call your doctor immediately
<p><b>The following side effects could mean you are having an allergic reaction. These side effects are rare.</b></p> <ul style="list-style-type: none"> <li>• A skin rash</li> <li>• Itching</li> <li>• Chest tightness</li> <li>• Wheezing</li> <li>• Dizziness</li> <li>• Hives</li> <li>• Faintness</li> <li>• Rapid heartbeat</li> <li>• Shortness of breath</li> <li>• A swollen face</li> </ul>	<ul style="list-style-type: none"> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> <li>✓</li> </ul>

Tell your doctor if you notice any of the following side effects and they worry you:

- Headache
- Runny or blocked nose
- Light-headedness
- Fever
- Chills
- Flushing
- Nausea
- Vomiting
- Diarrhea
- Feeling tired, drowsy or a lack of energy
- Discomfort or swelling at the injection site
- Altered taste
- Coughing
- Burning sensation in the jaw or skull
- Changes in your vision

These are all mild side effects of BeneFIX injection and will usually disappear on their own. Tell your doctor if you are concerned or if they continue.

***This is not a complete list of side effects. For any unexpected effects while taking BeneFIX, contact your doctor or hemophilia treatment centre.***

**HOW TO STORE IT**

***Before preparation (BeneFIX powder):***

Keep BeneFIX in the refrigerator (2°C to 8°C).  
DO NOT freeze.

If stored at room temperature below 25°C, BeneFIX must be used within 6 months. Write the date on the package when you first store BeneFIX at room temperature.

Keep BeneFIX (and needles) where young children cannot reach it.

BeneFIX must be used by the expiry date on the label. Do not use BeneFIX beyond the date (month and year) printed on the label after the word “Expires”, even if it has been stored properly.

***After preparation (BeneFIX solution):***

To avoid bacterial contamination of the solution, use the reconstituted BeneFIX as soon as possible or within 3 hours.

**REPORTING SUSPECTED SIDE EFFECTS**

**To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs . If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:**

**Toll-free telephone: 866-234-2345**

**Toll-free fax 866-678-6789**

**By email: [cadrpm@hc-sc.gc.ca](mailto:cadrpm@hc-sc.gc.ca)**

**By regular mail:**

**National AR Centre**

**Marketed Health Products Safety and Effectiveness**

**Information Division**

**Marketed Health Products Directorate**

**Tunney’s Pasture, AL 0701C**

**Ottawa ON K1A 0K9**

***NOTE: Before contacting Health Canada, you should contact your physician or hemophilia treatment centre.***

## **MORE INFORMATION**

**This document plus the full product monograph, prepared for health professionals, can be requested by contacting the sponsor, Wyeth Canada:**

**Medical Information: 1-800-461-8844**

**After Hours Emergency: 1-800-361-1336**

**This leaflet was prepared by Wyeth Canada.**

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