“IT’S SOMETHING I HAVE. NOT SOMETHING I AM.”
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**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.

Please see Important Safety Information on page 14 and accompanying full Prescribing Information.

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**Programs and Services**

Pfizer Hemophilia extends a special thanks to the B2B advisory board for their help in the creation of this brochure.
SECTION 1

BACKGROUND ON HEMOPHILIA

An important part of managing any health condition is having a clear awareness of the condition—this comes with education. In the case of hemophilia B, sorting through the specifics of treatment and life stages can be challenging without knowledge of the disorder itself. With this in mind, Pfizer Hemophilia has prepared this book as an informational resource for people and families living with hemophilia B.

NOTE: The information in this book should in no way replace the advice of a health care professional (HCP). Be sure to talk to your HCP, nurse, or hemophilia treatment center (HTC) staff regarding any form of medical advice and treatment.
What Are the Types of Hemophilia?

The type of hemophilia depends on which clotting factor is deficient or lacking in the blood.

Patients with hemophilia A or hemophilia B can present with similar signs and symptoms; however, each type is caused by a different clotting factor deficiency. Because of this difference, people with hemophilia A and people with hemophilia B are treated with different medications.

Hemophilia A is caused by a lack of clotting factor VIII.

Hemophilia B is caused by a lack of clotting factor IX.

Hemophilia A and hemophilia B are clinically similar, although type A is 4 to 6 times more common than type B.

What Are the Types of Bleeds?

Hemorrhages or “bles” may be caused by injury or may occur spontaneously (without any apparent cause). Hemophilia can range from mild to moderate to severe. Bleeds can begin in infancy, childhood, adolescence, or adulthood.

For more information, see the section “Types of Bleeds” on page 32.

Did You Know?

- Approximately 1 in 5,000 males has hemophilia.
- Hemophilia A occurs in about 80% to 85% of all hemophilia cases.
- Hemophilia B occurs in approximately 1 in 25,000 male births.
- All ethnic and racial groups appear to be equally affected.
Background on hemophilia

How Is Hemophilia Classified?
Hemophilia can be classified by the amount or level of clotting factor a person has. This determines the disorder severity.

<table>
<thead>
<tr>
<th>MILD HEMOPHILIA</th>
<th>MODERATE HEMOPHILIA</th>
<th>SEVERE HEMOPHILIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>factor levels between 5% and 40% of normal</td>
<td>factor levels between 1% and 5% of normal</td>
<td>factor levels less than 1% of normal</td>
</tr>
<tr>
<td>rare spontaneous bleeds; however, there may be excessive bleeding after trauma or surgery</td>
<td>occasional spontaneous bleeding and excessive bleeding after trauma or surgery</td>
<td>frequent spontaneous bleeding and continued bleeding after trauma or surgery</td>
</tr>
</tbody>
</table>

Disorder severity is classified by factor levels:
- 50% to 60% of people with hemophilia A have severe disorder
- 20% to 45% of people with hemophilia B have severe disorder

For a person without hemophilia, the normal range of factor VIII and factor IX in the blood is 50% to 150%. As with any average, for a biologic measurement, some people have higher levels, and others have lower levels.

Understanding the Blood-Clotting Process
Blood is a vital part of life. It carries oxygen and important nutrients to all of the tissues in the body. This process provides the body’s cells with sources of energy so they can function. Blood moves throughout the body in vessels within a network of tubes. The tubes are found throughout the body in joints, muscles, organs, and tissues. There are 3 varieties of blood vessels. Arteries carry blood away from the heart, capillaries connect arteries to veins, and veins carry blood back to the heart.

When someone injures a blood vessel through a bump, a bruise, or everyday wear and tear, the body will form a clot to stop the bleeding. This process is called coagulation—it keeps the blood inside the vessels. To form a clot, clotting factors act together with platelets in a series of reactions. The clotting factors make strong threads of fibrin that hold the clot together. This helps to close the injury and stop the bleeding.

If any clotting factors are missing or low, the body will have trouble stopping a bleed. This is what happens when someone has hemophilia. The clot does not form properly and bleeding continues.

Hemophilia History: A Timeline

~100 CE First mention of bleeding signs and symptoms; the Talmud says Jewish male infants were exempt from circumcision if older brothers had died as a result.
1800S Hemophilia gets the “royal treatment”; cases of hemophilia were reported in royal families of Europe.
1803 An inherited bleeding disorder: Dr. John Conrad Otto studied families and showed that bleeding signs and symptoms are passed along from mothers to sons.
1930S Discovery of clotting factor: 2 Harvard doctors discovered that blood from people without hemophilia contains something that can be used to help clotting in patients with hemophilia.
1940S Clotting factor tested: a doctor in Argentina performed a lab test showing that blood from one hemophilia patient could correct the clotting problem in another patient. It was unknown to the doctor that each patient had a different type of hemophilia.
1952 Hemophilia B (factor IX deficiency) is first distinguished from hemophilia A (factor VIII deficiency).
1960S Plasma was first used to replace missing clotting factor and treat hemophilia bleeds.
1985 First plasma-derived coagulation factor IX is approved.
1997 First recombinant factor IX product approved.

Please see Important Safety Information on page 14 and accompanying full Prescribing Information for BeneFix.
Hemophilia Is a Genetic Disorder

Certain genes help the body make clotting factor. When the gene for making clotting factor is abnormal, the body does not make enough factor. This is the reason why hemophilia is called a genetic disorder.

Hemophilia runs in families. In most cases, people are born with it. The genes for both factor VIII and factor IX are located on the X chromosome. Both hemophilia A and B are inherited as X-linked traits.

Chromosomes come in pairs—females have two X chromosomes, males have one X chromosome and one Y chromosome. The X chromosome carries the genes related to clotting factors. The Y chromosome does not.

A male with the abnormal gene on his X chromosome will have hemophilia. For a female to have hemophilia, she must have an abnormal gene on both of her X chromosomes, which is very rare.

A female is the “carrier” of hemophilia if she has the abnormal gene on one of her X chromosomes. Even though she does not have hemophilia, she can pass the gene on to her children. Females who are carriers usually have enough clotting factors from their one normal X chromosome to prevent serious bleeding problems. Some carriers choose to have their levels of clotting factor measured to determine whether they are at increased risk for clinical bleeding episodes.

Inheritance Patterns of Acquiring Hemophilia

Because it is inherited as a genetic defect on the X chromosome, the majority of people with hemophilia are males, but in rare cases, a girl can be born with hemophilia. This can happen if the father has hemophilia and the mother is a carrier.

Some males with hemophilia are born to mothers who are not carriers. In these cases, a mutation (random change) occurs in the gene as it is passed to the child.

Spontaneous Occurrence in Children

Hemophilia B is commonly caused by inheriting a genetic defect from a parent, most commonly the mother (see the figure to the right). However, about one third of the time, there is no family history and hemophilia B is caused by a spontaneous genetic mutation.

Genetic Defects in Hemophilia B

A number of different gene mutations are associated with hemophilia B. Most gene mutations in hemophilia B patients are missense or nonsense mutations. In missense mutations, the genetic defect causes the wrong amino acid to be inserted into the FIX protein, which prevents FIX from working properly. In nonsense mutations, the genetic defect causes production of the FIX protein to stop prematurely, resulting in an incomplete FIX protein that does not work properly.

What Is a Gene?

Genes carry information (DNA) that determines the traits a person will have, such as brown eyes or red hair. DNA makes every person different. Genes are located on chromosomes, which are found inside the cell nucleus. Genes can also control whether a person has hemophilia.

Background on hemophilia
By now you have gained a general understanding of what hemophilia, specifically hemophilia B, is and how the disorder can occur. In Section 2, we will discuss some of the treatment options currently available to people living with hemophilia B.

Treatment with any factor product should be managed under the supervision of an HCP who is experienced in the treatment of hemophilia B.
Treatment of hemophilia B

How Is Hemophilia B Treated?

One important goal of hemophilia B care is to treat bleeds as soon as they begin. As we previously learned, hemophilia B is caused by a low level of clotting factor IX in the blood. To correct this problem, treatment should begin with replacement of the missing clotting factor IX. Infusion of factor IX replacement products, also called “factor,” raises the level of clotting factor IX in the blood, allowing blood to clot properly.

There are 2 types of factor IX replacement products used to treat hemophilia B. Both products work in the same way to help replace the missing clotting factor IX, and both have proven to be effective.

The choices include:
- Plasma-derived factor IX concentrate
- Recombinant factor IX concentrate

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.

Selected 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.

Hemophilia Treatment: A Timeline

1911  Factor VIII was identified.
1930  Patients were treated with transfusions of whole-blood plasma. Researchers discovered that plasma precipitates given through intravenous (IV) infusions shortened clotting time.
1944  An American researcher developed fractionation, the process of separating plasma into its different parts.
1952  Factor IX was identified.
1955  The first therapy for hemophilia was developed using IV infusion of factor VIII.
1964  Cryoprecipitate (solid material, rich in clotting factor, that forms when plasma is frozen and then thawed) was discovered.
1980  Plasma-derived factor products were improved, purified, and treated to remove viruses. Genes for factor VIII and factor IX were cloned.
1989  The first clinical use of recombinant factor VIII occurred.
1992  Recombinant factor VIII products were approved by the FDA.
1997  The first recombinant factor IX product, BeneFix® Coagulation Factor IX [Recombinant], was approved.

Important
Factor replacement is a treatment, not a cure. After receiving factor, it lasts only a certain time and needs to be given again. People with hemophilia B need to use factor replacement throughout their lives to help control bleeding.

Please see Important Safety Information on page 14 and accompanying full Prescribing Information for BeneFix.
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 interfere with the effectiveness of BeneFix.
- 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 accompanying full Prescribing Information for BeneFix.

Need help paying for your Pfizer medicines?

Pfizer RSVP may be able to help, regardless of your insurance situation.

Call 1-888-327-RSVP (7787) or visit www.RSVP-program.com

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

SECTION 2

How Is BeneFix Made?

Recombinant techniques are when scientists take a gene, reproduce it, and transplant it into different cells. These cells are called host cells. They grow and multiply, and then produce the factor IX. BeneFix is manufactured through this process. In the case of BeneFix, the gene is the FIX gene and the host cells are Chinese hamster ovary (CHO) cells.

1982

1. After years of scientific research, the gene that codes for the production of factor IX was successfully recreated in a laboratory.

2. CHO cells were chosen as host cells because they multiply rapidly and produce large quantities of proteins. That’s one of the reasons they’ve been used in scientific study since the 1960s.

3. The recreated genes that code for the production of factor IX were then inserted into the CHO host cells.

4. After successful insertion of the gene, the CHO host cells were carefully nurtured to multiply.

5. The CHO cells produce large amounts of factor IX protein. The factor IX protein is separated out and purified.

6. After many years of testing in different organisms, animals, and people, BeneFix was approved for the treatment of hemophilia B.

Extensive monitoring and testing are performed to help ensure purity, potency, safety, and quality. Pfizer’s facilities have manufactured a supply of over 5 billion IU in order to meet the needs of the hemophilia B community.
BeneFix Convenience Features

BeneFix Rapid Reconstitution (R2) Kit provides a short and simple preparation process and offers added convenience for busy lives:

- **3000-IU** vial for fewer vials, less packaging waste, and faster cleanup—less packaging with the R2 Kit may reduce the amount of waste
- **Low 5-mL** diluent volume for all vial sizes
- Prefilled diluent syringe means fewer components and faster preparation
- Needleless rapid reconstitution to avoid risk of accidental punctures
- Infusion set with DEHP-free tubing and needle shield
- Clear vial adapter to easily confirm a good connection
- Color-coded vials for quick identification

Selected 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.

Please see Important Safety Information on page 14 and accompanying full Prescribing Information for BeneFix.
Reconstitution Steps

1. Let the vial of BeneFix and the prefilled diluent syringe reach room temperature.

2. Remove the plastic flip-top cap from the BeneFix vial to show the center part of the rubber stopper.

3. Wipe the top of the vial with the alcohol swab provided, or use another antiseptic solution, and allow to dry. After cleaning, do not touch the rubber stopper with your hand or allow it to touch any surface.

4. Peel back the cover from the clear plastic vial adapter package. Do not remove the adapter from the package.

5. Place the vial on a flat surface. While holding the adapter in the package, place the vial adapter over the vial. Press down firmly on the package until the adapter snaps into place on top of the vial, with the adapter spike penetrating the vial stopper.

6. Grasp the plunger rod as shown in the picture on the left. Do not touch the shaft of the plunger rod. Attach the threaded end of the plunger rod to the diluent syringe plunger by pushing and turning firmly.

7. Break off the tamper-resistant, plastic-tip cap from the diluent syringe by snapping the perforation of the cap. Do not touch the inside of the cap or the syringe tip. The diluent syringe may need to be recapped (ie, if reconstituted BeneFix is not used immediately), so place the cap on its tip on a clean surface in a spot where it will stay clean.

8. Place the vial on a flat surface. Connect the diluent syringe to the vial adapter by inserting the tip of the syringe into the adapter opening while firmly pushing and turning the syringe clockwise until the connection is secured.

9. Slowly push the plunger rod to inject all the diluent into the BeneFix vial.

10. With the syringe still connected to the adapter, gently swirl the contents of the vial until the powder is dissolved. Look at the final solution before infusing it. The solution should be clear to colorless. If it is not, throw away the solution and use a new kit.

11. Make sure the syringe plunger rod is still fully pressed down, then turn over the vial. Slowly pull the solution into the syringe. Turn the syringe upward again and remove any air bubbles by gently tapping the syringe with your finger and slowly pushing air out of the syringe. If you reconstituted more than one vial of BeneFix, remove the diluent syringe from the vial adapter and leave the vial adapter attached to the vial. Quickly attach a separate large luer lock syringe and pull the reconstituted solution as instructed above. Repeat this procedure with each vial in turn. Do not detach the diluent syringes or the large luer lock syringe until you are ready to attach the large luer lock syringe to the next vial adapter.

12. Remove the syringe from the vial adapter by gently pulling and turning the syringe counter-clockwise. Throw away the vial with the adapter attached.

If you are not using the solution right away, you should carefully replace the syringe cap. Do not touch the syringe tip or the inside of the cap. BeneFix should be infused within 3 hours after reconstitution. The reconstituted solution may be stored at room temperature prior to infusion.

Please see Important Safety Information on page 14 and accompanying full Prescribing Information for BeneFix.
Treatment of hemophilia B

Same Formulation, Room Temperature Storage
BeneFix is approved by the US Food and Drug Administration (FDA) to be stored at room temperature or under refrigeration (2°C to 30°C/36°F to 86°F) for up to 2 years until expiration. BeneFix has the same formulation with a room storage condition.

How Much to Infuse—Factor Dosing
Only your HCP can decide on the proper dose of BeneFix that will work best for you. He or she will base the recommended dosage for you on the following information:

- The seriousness of the bleed and its location
- The severity of the factor IX deficiency
- Your weight and age
- Recovery of factor IX

Percentage of Circulating Factor IX Activity Generally Considered to Be Needed for the Body to Respond to Types of Bleeding Episodes
The goal of factor IX therapy is to replace the missing factor so that there is enough factor IX in the blood to stop a bleed. Some bleeds may stop after one dose, while others may need several infusions to stop. Severe bleeds may even need therapy once or twice a day for several days. Follow treatment plan prescribed by your HCP.

How Often to Infuse—Dosing Schedule
In general, there are several dosing schedules for the treatment of hemophilia B with factor therapy. Some of them are as follows:

- On-demand therapy involves giving factor infusions when a bleed begins
- Preventive infusions are given prior to an event that may cause bleeding
- HCPs prescribe dosing schedules to meet the needs of their patients

Selected Safety Information for BeneFix

- 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.

Please see Important Safety Information on page 14 and accompanying full Prescribing Information for BeneFix.
Treatment of hemophilia B

Important Information About Factor Replacement

After an infusion, your HCP may measure or keep track of the amount of factor IX in your blood. One such measure is called recovery. Recovery is important to know because it helps your HCP determine the proper dose of factor your body needs. Recovery is measured by taking a blood test, also called an assay.

Recovery is different for every person and may change for you over time. It can be influenced by age and weight and differs based on the factor product used.

Using an Infusion Log

To remember the details about when and how you infused, you need a place to write down the information. An infusion log is a book used to record your factor treatments. This log helps you record how you treat your hemophilia B between HCP visits. Using an infusion log similar to one on page 23 can help you keep track of important medical information, such as:

- How much factor was given
- Products used and when
- How often factor was given
- Side effects or problems

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

Selected Safety Information for 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.
- Some common side effects of BeneFix are nausea, injection site reaction, injection site pain, headache, dizziness and rash.

Please see Important Safety Information on page 14 and accompanying full Prescribing Information for BeneFix.
Important Inhibitor Information

An inhibitor is an antibody that develops in direct response to infused clotting factor concentrates. As a result of this rare complication, standard treatment is temporarily made less effective.

- An inhibitor is something that stops or blocks another substance. In hemophilia B, inhibitors are antibodies that stop clotting factor replacement medicine from helping to form a blood clot.
  - Inhibitors can be transient (do not last long) or persistent (last for a long time).
  - If the inhibitor is persistent, your HCP may need to adjust the dose of clotting factor replacement medicine, try immune tolerance induction therapy, or use bypass clotting factor replacement therapy.
- One sign that an inhibitor may have developed is when clotting factor replacement medicine does not work as it usually has in the past.
- Your HCP may also discover an inhibitor that your child has developed during a routine blood test (Bethesda assay) during annual physical exams.
  - If you think you or your child may have developed an inhibitor, talk to your HCP.

IN A STUDY
1 out of 65 (1.5%) previous BeneFix users developed a low-titer, transient inhibitor

- The patient continued on study.
- At study completion (approximately 15 months after inhibitor detection), the inhibitor was temporary.

2 of 63 (3.2%) new BeneFix users developed high-titer (>5 BU) inhibitors

- Both were withdrawn from the study.

Where to Go for Treatment

Hemophilia Treatment Centers (HTCs) provide comprehensive care for people with bleeding disorders. Comprehensive care means that a person’s medical, social, and emotional needs are all addressed. Care at an HTC is in addition to the care you receive from family and HCPs.

HTCs are located all over the United States; some HTCs are located internationally. See the section “To Locate an HTC Near You” on page 27 for more information.

HTCs provide many services, including supply and delivery of factor, home infusion education, dental care, home visits by social workers, and insurance counseling. Many types of specialists work together to meet the challenges a person with a bleeding disorder may encounter.

Please see Important Safety Information on page 14 and accompanying full Prescribing Information for BeneFix.
TREATMENT OF HEMOPHILIA B

WHO’S WHO AT YOUR HTC

Here is a list of people who may be involved in caring for you when you visit an HTC.

- Hematologists: doctors who specialize in bleeding disorders and oversee patient care
- Pediatricians: doctors who specialize in the care of children
- Hemophilia nurses: specialists in hemophilia care who work closely with patients to give treatment
- Orthopedist: surgeons who work closely with the HTC in managing skeletal disease resulting from repeated bleeding episodes
- Physical therapists: specialists in activity, exercise, and rehabilitation
- Social workers: counseling specialists who help you with issues of daily living and with locating resources
- Genetic counselors: professionals who counsel families about carrier testing and prenatal diagnosis of genetic disorders such as hemophilia
- Dentists: some HTCs have dentists who are specially trained to treat people with bleeding disorders

TO LOCATE AN HTC NEAR YOU

1. Use the HTC locator at www.HemophiliaVillage.com or BeneFx.com

OR

2. Contact HANDI, the informational branch of the National Hemophilia Foundation (NHF), at 800-42-HANDI (800-424-2634) by e-mail at handi@hemophilia.org or visit their Web site at www.hemophilia.org

OR


Please see Important Safety Information on page 14 and accompanying full Prescribing Information for BeneFx.
I learned early that my factor can help keep me in the game.

SECTION 3

HEMOPHILIA B: WHAT TO EXPECT

We have now discussed hemophilia B—how people acquire the disorder and how it is treated. There is still much to discuss, including the different types of bleeds a person with hemophilia B can experience and how to determine their severity. The level of severity depends on the location of the bleed in the body and the cause of the occurrence.

We will also talk a little about lifestyle and how hemophilia B impacts life stages from infancy into the teenage years. We hope to shed some light on what might be expected when living with hemophilia B.
What Are the Signs and Symptoms of Hemophilia B?

An accurate diagnosis of hemophilia B is the first essential step to hemophilia B care. Bleeding is the most common symptom of hemophilia B. When people with hemophilia B are injured, they do not bleed faster than a person without hemophilia B, just longer. They may also start bleeding again several days after an injury or surgery. For a person with hemophilia B, small cuts or surface bruises are usually not a problem, but deeper injuries may result in bleeding episodes that could cause serious problems and lead to permanent disability unless treated promptly.

Hemophilia B: what to expect

The signs and symptoms of hemophilia B bleeds depend on where the bleed is occurring. The signs and symptoms of bleeds include:

- Pain
- Swelling
- Loss of range of motion in a joint
- Inability to move or use the affected arm or leg
- There might not be bruising or discoloration of the skin to indicate that the swelling and pain are due to bleeding

Other signs and symptoms of hemophilia B include:

- Easy bruising; people may have many bruises of different sizes all over their bodies
- Prolonged nosebleed
- Vomiting of blood

Hemorrhages or “bleeds” may be caused by injury or may occur spontaneously (without any apparent cause). Bleeds can begin in infancy, childhood, adolescence, or adulthood. Depending on the severity of the underlying bleeding disorder, bleeding episodes may be frequent to rare or only occur with surgery or other procedures.

It’s important that you learn to recognize the signs and symptoms of a bleed at the earliest possible time and treat appropriately.
Hemophilia B: what to expect

Types of Bleeds

Intracranial or Head Bleeds
A bleed into the brain is very serious. The signs and symptoms include headache, blurred vision, nausea or vomiting, mood or personality changes, drowsiness, loss of balance or coordination, weakness or clumsiness, stiffness of the neck, loss of consciousness, and seizures.

Nose, Mouth, and Throat Injuries
Injury or infection in the nose, mouth, or throat causes blood to fill the tissues. As the tissues swell with blood, they can press on the airway, making it smaller or closing it completely. It is important to watch out for pain in the neck or throat, swelling, difficulty swallowing, and difficulty breathing.

Joint Bleeds
Joint bleeds, also called hemarthroses, are one of the most common kinds of bleeding for a person with hemophilia. A joint bleed may begin with a warm, tingling, and/or bubbling feeling that is usually followed by pain, decreased movement, and swelling of the joint. Recurring bleeds in a joint can cause permanent damage by destroying the synovial membrane (the soft tissue between the joint capsule and joint cavity of synovial joints) and the cartilage at the end of bones.

Chest Injuries
Injury to the chest may cause bleeding in the lungs, heart, and major blood vessels. Bleeding in the lung tissues forces blood into airways, making it difficult to breathe. Signs and symptoms are pain in the chest and difficulty breathing.

Abdomen
Injury to the belly area, including internal organs such as the stomach, spleen, liver, kidneys, and intestines, could result in massive bleeding from an organ or major blood vessel. Pain in the abdomen or lower back, nausea, and/or vomiting are concerning signs and symptoms.

Urinary Tract Bleeds
Many people with hemophilia B have bleeding in the urinary tract, also called hematuria. Another concerning symptom includes dark red urine.

Iliopsoas Bleeds
Iliopsoas bleeds occur in the muscles of the back and pelvic area, near the hip. This type of bleed can damage the nerves of the thigh muscle, thereby limiting a person's movement. If an iliopsoas bleed is left untreated, it can cause heavy blood loss and permanent damage.

Compartment Bleeds
Compartments are closed-in spaces, such as those in the forearm or calf muscles. When a person bleeds deep inside these closed spaces, the blood puts pressure on the nerves and blood vessels within the muscle. If left untreated, compartment bleeds can cause permanent nerve damage and sometimes a loss of limb. Signs and symptoms to watch for include pain and tingling in the fingers or toes.

Brusing
Bruises are another common bleeding symptom in people with hemophilia B. Some bruises can be mild and heal on their own with ice, and others may not. Please seek medical attention for bruises that are very painful, grow larger over time, limit movement, or affect sensitive critical areas.

Mouth Bleeds
Mouth bleeds, such as those caused by biting the lip or tongue, new teeth coming in, or a dental procedure, are very common in people with hemophilia B. They can be very serious because persistent mouth bleeding can cause severe anemia.

Please speak with a medical professional to learn when to seek medical care.
Hemophilia B: what to expect

Preparing for Emergencies

It can be difficult for patients with hemophilia B to achieve and maintain a normal level of factor IX to prevent all potential hemorrhages. People with hemophilia B are at risk for severe bleeding that may lead to serious or life-threatening circumstances requiring emergency care.

People with hemophilia B, or parents of children with hemophilia B, are in the best position to manage their health or their child’s health.

• Learn as much as possible about hemophilia B
• Learn what to do if a bleeding situation may be happening

Health care professionals in the emergency room (ER) will ask to be provided with information on the hemophilia B patient’s past and current medical history. Be prepared to answer their questions.

Recognizing an Emergency Situation

There may be no visible signs or symptoms of bleeding in a person with hemophilia B, but bleeding issues, such as head injuries, muscle bleeds, and trauma can be serious. Emergency bleeding events require recognition and immediate intervention with factor replacement products to replace the missing factor IX in the blood and restore normal blood clotting.

The following are some examples of situations typically requiring factor replacement therapy:

• Any signs or symptoms of bleeding in the brain. Such bleeding is life threatening and requires immediate emergency care
• Significant injury to the head, muscles, neck, mouth, or eyes, or evidence of bleeding in those areas. Such bleeding can be life threatening and may require immediate emergency care
• New or unusual headache, particularly one following trauma. Such bleeding can be life threatening and may require immediate emergency care
• Severe pain or swelling at any site. Such bleeding can be life threatening and may require immediate emergency care
• Open wounds requiring surgical closure, wound adhesive, or steri-strips. Such bleeding can be life threatening and may require immediate emergency care
• History of an accident or a trauma that might result in internal bleeding. Such bleeding can be life threatening and may require immediate emergency care
• Invasive procedure or surgery
• Heavy or persistent bleeding from any site. Such bleeding can be life threatening and may require immediate emergency care
• Gastrointestinal bleeding. Such bleeding can be life threatening and may require immediate emergency care
• Acute fractures, dislocations, and sprains. Such bleeding can be life threatening and may require immediate emergency care
• Limited motion, pain, or swelling of any area
Infusion Log

It’s a good idea to keep a log of all previous treatments. Be sure to take this log to all medical appointments and to the hospital or ER.

See “Sample Daily Infusion Log” on page 23.

R.I.C.E.

Bleeds in the muscles or soft tissues can be treated by using a form of first aid called R.I.C.E.

- **R** can also mean Replacement of clotting factor. During a bleed, the affected area should be rested—no walking if the bleed is in the knee, no lifting if the bleed is in the elbow.

- To lessen pain or swelling, apply ice to the affected area—10 to 15 minutes every 2 hours is recommended.

- Applying pressure (compression) to the area can also help to slow the bleeding—such as using an elastic bandage. Always check with your local HTC for the proper way to apply the bandage.

- Elevating or raising the injured limb (arm or leg) above the heart will help to slow the bleeding.

It is always a good idea to check with an HCP if there are any questions about how to control a bleed.

### Important Points to Remember When Emergency Care Is Needed

Clotting factor concentrates might not be kept on hand at all hospitals. If you do not have factor with you, there may be a delay in obtaining factor concentrate.

- Have an emergency dose of clotting factor concentrate in your home at all times

- Take your factor IX with you when you travel and/or if you go to the ER

- The ER personnel may ask you if you have your own factor IX with you, and they may ask you to infuse the dose

### What to Take When You Go to the Emergency Department (ED)

- Clotting factor IX and infusion supplies

- HCP’s phone number in case the ED personnel need to speak to him or her

- Information about hemophilia B—the ED staff may have little experience with hemophilia B and may ask you about your or your child’s treatment

- Your infusion log

Carry a letter from your or your child’s HCP describing your or your child’s hemophilia B and your or your child’s treatment. Find out in advance where to go for care when you’re out of town.

Use the HTC locator at [www.HemophiliaVillage.com](http://www.HemophiliaVillage.com) to find local HTCs when out of town.
When Surgery Is Needed

The following issues should be considered according to the World Federation of Hemophilia (WFH):

- Surgical procedures should be performed in coordination with a team experienced in the management of hemophilia B
- Procedures should take place in a center with adequate laboratory support for reliable monitoring of clotting factor levels
- Preoperative assessment should include inhibitor screening
- About 10% to 15% of hemophilia A patients and 1% to 3% of hemophilia B patients may develop persistent inhibitors rendering treatments with factor concentrates difficult
- Availability of sufficient quantities of clotting factor concentrates should be ensured before undertaking major surgery for hemophilia B patients
- The dosage and duration of clotting factor concentrate coverage depends on the type of surgery being performed
- Surgery should be scheduled early in the week and early in the day for optimal laboratory and blood bank support, if needed

Clotting factor replacement is often given before, during, and after surgery to help prevent excessive bleeding. Please speak with your medical team before you undergo surgery and ask any questions you might have. It is important that your surgeon has experience in operating on people with bleeding disorders and that he or she understands your individual needs. Check with your local HTC for additional information.

Hemophilia B in Infants and Toddlers

Dental Hygiene

As a child ages, dental hygiene is very important. Mouth bleeds are possible as children lose their baby teeth and adult teeth appear. Maintaining a clean, healthy mouth is important to help prevent infection. It is also important to help prevent gum disease, which can cause bleeding in the mouth.

All children should see the dentist for regular visits, especially those children with hemophilia B. It is important for the dentist to be aware of a child’s hemophilia B. The dentist should always check with the hemophilia team when planning any dental work. Prior treatment with factor may be needed.

Learning to Walk

Bleeding often becomes an issue when toddlers begin to stand and walk, putting weight on their legs for the very first time. During the time when children are learning to walk, they get plenty of bumps and bruises. A child with hemophilia B should be watched carefully to make sure these bumps and bruises are not serious.

The following list offers some steps you can take to make sure your home is safe for a child:

- Place safety gates at the top and the bottom of all stairs
- Place padding on the corners of coffee tables, fireplaces, and other furniture
- Keep all sharp objects, such as knives and scissors, out of a child’s reach
- Remove loose floor rugs that can cause a child to slip or trip
- Do not use a baby walker
- Cover all electrical outlets
- Keep guns, choking hazards, and toxic, hot, and sharp items out of reach
- Never leave young children unattended in a bath
- Install smoke detectors
- Install knob covers on doors to nonchild-proofed areas
- Don’t put soft bedding or toys in cribs
Babysitters

When you leave a child with hemophilia B with another person, or when the child plays with other children, make sure that the person in charge is aware of the child’s bleeding disorder. More importantly, make sure that the person in charge knows what to do if the child should become injured. Ensure that this person has a general understanding of what hemophilia B is and the types of bleeds the child may have. Write down all instructions you believe are important, and advise the person NOT to give the child any prescription or nonprescription medications without your approval.

The instructions you leave may include:

- The signs and symptoms of a bleed
- The child’s limitations—what the child can and cannot do
- Number(s) where you can be reached in case of an emergency
- Emergency contact names and phone numbers—your HCP and the local HTC

Talk to Your HCP About Pain or Anti-Inflammatory Medicines

When a child with hemophilia B has pain, it is important to follow the HCP’s instructions for which medicines you can give to treat the pain. People with hemophilia B should not take aspirin (ASA or acetylsalicylic acid) or products that contain aspirin. These products cause the blood to thin and make it difficult for a clot to form—this promotes bleeding. Be sure to read all prescription and nonprescription labels before giving the child medicine. Some anti-inflammatory medicines such as ibuprofen (Advil®, Motrin®) and naproxen (Aleve®) can also interfere with the clotting process. Make sure to check with your HCP to find out which products are safe for the child to take.

Helping School Staff to Understand

To ease this transition, you should speak with people who will be caring for the child at school. Introduce yourself to the school principal, the teachers, and the school nurse. Provide them with all the facts about the child’s hemophilia B. Because many people are not familiar with hemophilia B, you may find yourself having to educate them. Reassure them that hemophilia B is not contagious. It may be helpful to arrange a meeting between the school staff and a member from the local HTC.

Things to Make the School Aware of:

- Any physical restrictions or limitations a child may have
- A child’s medications and how they are used
- Signs and symptoms of a bleed and how to treat it
- Names and phone numbers for emergency contacts, such as your HCP and local HTC
- Where you can be reached during the day
Hemophilia B: what to expect

Social Reassurance

No child wants to stand out as different or needy among his peers. To help the school understand the child’s bleeding disorder and his or her potential needs, explain to staff that being overprotective is not necessary. Let the school know in which activities the child can participate. If there are special needs, discuss how to handle them in a less noticeable manner.

If a child should have a bleed while at school, advise the staff ahead of time that the bleed will need to be treated immediately. A child with hemophilia B who is injured should always be given prompt attention, and the staff must contact you right away. You may have to go to the school to give your child an infusion.

If you are still feeling uneasy about your child attending school, it may help you to speak with other parents in your area who have children with hemophilia B. Discussing your feelings and these issues with other people in a similar situation might help you to feel more confident. Support groups with parents of children with hemophilia B can be found at your HTC.

Hemophilia B in the Preteen Years

As children move from childhood to preadolescence they face new challenges, including heightened peer acceptance. Preteens with hemophilia B need to be reminded that having hemophilia B does not determine who they are or what they will become. Instead of focusing on what they cannot do, they need to learn to focus on their strengths and abilities. It is important for them to become involved with hobbies and activities, such as art or music.

By the time children become preteens, they are generally capable of thinking logically and seeing the cause and effect of situations. They will be able to report when they have a bleed. They will begin to understand that certain activities are more likely to cause bleeds than others, and they can be encouraged to be cautious about those activities.

During this age, children are aware of adult feelings. If you react to their bleeds with anger, fear, and frustration, they may try to “protect” you by not telling you about a bleed until the pain becomes hard to bear.

Parents should respond to bleeds in a measured, reassuring way. For example, you may say, “I’m sorry you’re hurt, and I’m glad you told me you had a bleed. Let’s get your treatment started so you can feel better.”

Parents of preteens often find it difficult to set limits for the child’s activities. Permissive parents may feel sorry for their child and try to “make it up to him” by not setting appropriate boundaries. Overprotective parents may set too many limits and monitor their child’s every move in an effort to keep him safe.

Preteens need both clear and consistent rules and the freedom to develop their own interests and abilities. For example, by establishing the rule “no hitting” between your child and his playmates, difficulties may be avoided later. As long as no one is hitting, try to avoid jumping in to settle every argument that arises. Let the child learn different ways to resolve conflict.

Need More Info?

The National Hemophilia Foundation (NHF) has information to educate school staff members about hemophilia B. To obtain free HANDI publications, contact the NHF at 1-800-42-HANDI or go online to www.hemophilia.org. You can also look for educational publications at your local HTC.
LIVING with hemophilia B

Hemophilia B in the Teenage Years

The transition from preteen to teenager can be a challenging time for parents and for their children. A teenage child may want more freedom and independence, more privacy, and may not talk as openly as they once did. It may be harder to keep the lines of communication open.

By the time preteens become teenagers, they may know as much about hemophilia B as the parent. If the teen is self-infusing, he is already beginning to manage his own treatment. He may ask to visit his HCP on his own and speak privately with his medical team.

The teenage years represent transitional times for adolescents; they are trying to figure out who they are and what they want to do with their lives. A teenager may have friends who think his factor treatment is different and feel a little out of place at times. By the time preteens become teenagers, they may know as much about hemophilia B as the parent. If the teen is self-infusing, he is already beginning to manage his own treatment. He may ask to visit his HCP on his own and speak privately with his medical team.

Good Nutrition

Young adults on their own must learn how to cook healthy foods for themselves. People with hemophilia B need to maintain a healthy diet to help ensure wellness.

Transitioning From Adolescence to Adulthood

Health Costs

The economic issues of the high costs of managing hemophilia B over a lifetime necessitate that every young adult with hemophilia B learn certain financial basics—budgeting, applying for medical insurance, and handling insurance claims and coverage. At what age will they no longer be covered under your insurance? What type of insurance will they be able to obtain when they must look for coverage on their own? Before accepting a job, they must review the insurance offered to make sure that their hemophilia B treatment will be covered.

Good Nutrition

Young adults on their own must learn how to cook healthy foods for themselves. People with hemophilia B need to maintain a healthy diet to help ensure wellness.

Need More Info?

The National Hemophilia Foundation (NHF) has information to educate school staff members about hemophilia B. To obtain free HANDI publications, contact the NHF at 1-800-42-HANDI or go online to www.hemophilia.org. You can also look for educational publications at your local HTC.
Hemophilia B: what to expect

Mental and Physical Health

Helping Your Child’s Confidence

Many children have self-esteem issues at some point in their lives. These feelings can stem from not liking things about themselves, such as their body or their personality. They may lack confidence in their own ability to do anything. Self-esteem issues can be caused by a feeling of not fitting in with their peers. These types of feelings become magnified when children have hemophilia B because they may feel that the hemophilia B makes them very different from other children. They may even blame themselves for having hemophilia B, causing additional negative feelings to develop.

You can help your child with these self-esteem issues by speaking with him on a regular basis and becoming a source of support and comfort. When children feel good about themselves, they have an easier time handling pressure and conflicts in their lives.

Staying Fit

Maintaining physical activity is important for all children. It is especially important for children with hemophilia B because building strong muscles can help protect joints from bleeds. Exercise helps to build strength and flexibility, both of which aid in preventing injuries. It is also good for the mind and assists in building a child’s confidence. Taking part in sports can teach teamwork and develop self-esteem. Exercise develops healthy lifestyle habits that can be carried through a person’s life. There are limitations, however, because some activities might be risky to a person with hemophilia B.

It’s important to consult an HCP before participating in any sports activity.

Need More Info?
The National Hemophilia Foundation (NHF) has information to educate school staff members about hemophilia B. To obtain free HANDI publications, contact the NHF at 1-800-42-HANDI or go online to www.hemophilia.org. You can also look for educational publications at your local HTC.

NATIONAL HEMOPHILIA FOUNDATION (NHF)
SPORTS RATINGS BY ACTIVITY

NHF does not recommend any sports activities rated 3.0 for people with bleeding disorders.

<table>
<thead>
<tr>
<th>SAFE</th>
<th>SAFE/MODERATE</th>
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<th>MODERATE/ DANGEROUS</th>
<th>DANGEROUS</th>
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<tr>
<td>1.0 RATING</td>
<td>aquatics</td>
<td>archery</td>
<td>elliptical machine fishing Frisbee® disc golf</td>
<td>1.5 RATING</td>
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</table>
Exercising is important for anyone with hemophilia B. It can help increase muscle strength, joint mobility, balance, coordination, and flexibility—all important to help protect the body from injuries. Any exercise routine should always begin with stretching. This will help prepare the muscles and prevent them from being injured during the workout.

In addition to the physical benefits, there are psychological and social benefits from exercise, such as increased relaxation, improved self-esteem, self-image, and mood, and an increase in feelings of acceptance and belonging to a group of peers.

Talk with the physical therapist at your local HTC about an exercise program that meets your or your child’s needs. With a graduated exercise program, most of the chronic postural changes that occur in people with hemophilia B can be avoided. By maintaining mobile joints and strong, flexible muscles, people with hemophilia B should be able to continue with regular daily activities at home, school, and work.

Eating Right

Part of staying fit includes eating right—eating a well-balanced diet that includes plenty of fresh fruits and vegetables. Check with your local HTC for more information about nutrition. Maintaining a healthy weight is important for anyone with hemophilia B, not just children. Being overweight can put additional pressure and stress on joints, such as knees and ankles. The additional pressure and stress can cause damage to the padding between the joints, or cartilage. Over time, a person can develop a painful, mobility-limiting joint condition called arthritis.

Eating right can also help prevent diabetes and heart disease—health problems that can put added stress on the body and complicate a person’s overall condition.

For additional information about nutrition, visit www.health.gov/dietaryguidelines.

Conclusion

Science and technology have made great strides over the years in improving hemophilia B treatment.

We hope you were able to benefit from the information and advice provided in this book. Understandably, you may have many more questions about hemophilia B and other topics discussed in this book. There are numerous resources and support services available that can help you sort through the details. You should take advantage of every opportunity to become more knowledgeable about hemophilia B.
Programs and Services

Pfizer Hemophilia Hotline
This hotline answers questions about Pfizer’s products and services:
1-888-999-2349

Pfizer RSVP Program
RSVP—the Reimbursement Solutions, Verification, and Payment HELPline—is a reimbursement support service and patient assistance program designed to help patients gain access to the Pfizer medicines they need:
1-888-327-RSVP (7787)

Summer Camp Support
Pfizer sponsors camp information conferences, provides financial assistance for scholarships to camp, and donates emergency factor for campers. We know how important it is for children with hemophilia to make new friends and enjoy themselves with people who understand their disorder.

Soozie Courter “Sharing a Brighter Tomorrow” Hemophilia Scholarship Program
Pfizer provides scholarships to students with hemophilia A or hemophilia B who are high school seniors, have a graduate equivalency diploma (GED), or are currently enrolled in an accredited junior college, college (undergraduate or graduate), or vocational school. Awards are based on academics, recommendations, and a personal statement from the student. Visit www.HemophiliaVillage.com to download an application.

HemophiliaVillage.com
The Pfizer-sponsored Web site, www.HemophiliaVillage.com, provides information for the hemophilia community. Consumers and professionals alike can find product information and learn about programs and services.

World Federation of Hemophilia (WFH) Twinning Program
Pfizer is an exclusive sponsor of this program, which links HTCs in developed countries, such as the United States, with countries that have limited medical resources. The goal of the program is to help improve hemophilia care worldwide. For more information about this program, call 1-514-875-7964, or visit the Web site at www.wfh.org.

Pfizer Factor Savings Card
The Pfizer Factor Savings Card helps commercially insured patients gain access to Pfizer factor products through reimbursement support services and the patient assistance program. The Pfizer Factor Savings Card can help cover the cost of out-of-pocket co-pays, deductibles, and coinsurance associated with Pfizer factor products.
www.HemophiliaVillage.com

Pfizer Hemophilia Trial Prescription Program
Appropriate patients may be eligible to receive a 1-month supply up to 20,000 IU of recombinant therapy at no cost. Terms and Conditions apply.

Resources

Arizona Hemophilia Association
North American Camping Conference of Hemophilia Organizations (NACCHO)
Phone: 1-888-754-7017
Web site: www.naccho.com

Canadian Hemophilia Society
Phone: 1-800-668-2686
Web site: www.hemophilia.ca

Centers for Disease Control and Prevention (CDC)
Hemophilia Treatment Centers
Web site: www.cdc.gov/ncbddd/hemophilia/HTC.html

The Coalition for Hemophilia B, Inc.
Phone: 1-212-520-8272
Web site: www.coalitionforhemophilia.org

Hemophilia Federation of America (HFA)
Phone: 1-800-230-9797
Web site: www.hemophiliafed.org

National Heart, Lung, and Blood Institute (NHLBI)
Phone: 1-301-592-8573
Web site: www.nhlbi.nih.gov

National Hemophilia Foundation (NHF)
Phone: 1-800-426-2634 (42-HANDI)
Web site: www.hemophilia.org

Patient Services Inc. (PSI)
Phone: 1-800-366-7741
Web site: www.patientservicesinc.org

World Federation of Hemophilia (WFH)
Phone: 1-514-875-7944
Web site: www.wfh.org

Mind Over Matters
This serialized graphic story will provide hemophilia B patients and caregivers with stories that they can relate to based on their experience with hemophilia. Each installment will feature a graphic story that depicts a situation that is unique and recognizable by the hemophilia community. Individuals who are currently enrolled in Hemophilia Village will receive an intriguing glimpse of the story and will be able to visit the micro site that contains the full story and interactive options, such as:

B2B Books
These are a series of life-based booklets that address challenges faced by hemophilia B patients through various life stages, from childhood through preteen, and from teen to adulthood.
Daily Infusion Log

Date ___________________________ Time __________ AM PM

Product ___________________________

Place vial stickers here

Total # units ___________________________

Reason for infusion

☐ Prevention Activity/Event ___________________________

☐ Bleed/Injury Location ___________________________

☐ Bleeding Symptom(s) ___________________________

☐ Follow-up Scheduled ___________________________

Notes ___________________________

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Hemophilia