BeneFIX®

nonacog alfa (rch) (recombinant coagulation factor IX), 250, 500, 1000, 2000, 3000 IU /vial
Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about BeneFIX. It does not contain all of the available information. It does not take the place of talking to your doctor or hospital pharmacist.

If you have any concerns about using BeneFIX, ask your doctor or hospital pharmacist.

Your doctor and hospital pharmacist have more information.

Keep this leaflet with your BeneFIX.

You may need to read it again.

What BeneFIX is

BeneFIX, nonacog alfa (rch) is a coagulation factor IX product that is produced by recombinant technology. Mammalian cells, which have the DNA for human coagulation factor IX put in them, are grown in large amounts in cell culture laboratories. These cells make recombinant human factor IX, which is released into cell culture media and then very highly purified. The recombinant factor IX does not contain any human blood, preservatives, or added animal or human components.

What BeneFIX is used for

People with haemophilia B (Christmas disease) are deficient in coagulation factor IX. BeneFIX works by replacing factor IX to enable blood to clot.

BeneFIX is used for the control and treatment of bleeding and the prevention of bleeding in people with haemophilia B.

BeneFIX has been approved for use in haemophilia B. Ask your doctor if you have any questions about why BeneFIX has been prescribed for you.

There is no evidence that BeneFIX is addictive.

BeneFIX is not expected to affect your ability to drive a car or operate machinery.

Before you use BeneFIX

When you must not use it
Do not use BeneFIX if you are allergic to hamster proteins or any of the ingredients listed at the end of this leaflet.

Signs of allergy include a skin rash, itching, chest tightness, wheezing, dizziness, hives, faintness, rapid heartbeat, blurred vision, shortness of breath and/or a swollen face. If any of these signs occur, stop using BeneFIX and see your doctor immediately, you may need urgent medical care.

Do not use BeneFIX after the expiry date (printed on the pack).

If you use this medicine after the expiry date has passed, it may not work as 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.

Before you start to use it
Certain people must use BeneFIX with caution. Ask your doctor for advice.

Tell your doctor if you:
1. **are pregnant or planning to become pregnant.**
   It is not known whether BeneFIX can affect your ability to have children or harm your developing baby.

2. **are breast feeding or planning to breast-feed.**
   It is not known whether BeneFIX passes into breast milk.

3. **have liver disease or are at risk of developing clotting disorders other than haemophilia or have recently had surgery.**
   These conditions increase your risk for clotting complications.

Taking other medicines
Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by BeneFIX, or may affect how well it works. You may need to use different amounts of your medicine or you may need to take different medicines. Your doctor will advise you.

Using BeneFIX

How BeneFIX is given
BeneFIX is given as an injection directly into your veins, usually by yourself, a doctor, nurse, or other trained person.

BeneFIX contains no additives that would prevent the growth of bacteria once the powder is dissolved with sterile sodium chloride solution. For this reason, each vial of BeneFIX is for single use only, in one patient only. Discard any residue.

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

When injecting BeneFIX, you must follow the detailed instructions provided in the leaflet inside the pack.

When you have finished injecting BeneFIX, discard the needle and syringe into a sharps container.

If you do not understand the instructions for injecting BeneFIX found in the pack, ask your doctor or pharmacist for help.

Dosage
Your doctor will decide the dose of BeneFIX you will receive. The dose and duration will depend upon your individual needs for replacement factor IX therapy. If you have been using plasma-derived factor IX, the dose of BeneFIX may differ from the dose of plasma-derived factor IX.

Your doctor may decide to change the dose of BeneFIX you receive during your treatment.

Reconstitution and administration of BeneFIX
Always wash your hands before doing the following procedures. Use germ-free methods during the making up procedure and during injection.

Use only the materials provided in the pack for dissolving the BeneFIX powder with the sodium chloride solution and then injecting the BeneFIX solution.

Inject BeneFIX solution as soon as possible or within 3 hours after dissolving the powder.

The made-up solution may be stored at room temperature before injection.

Inject the BeneFIX solution intravenously over several minutes.

The rate of injection should be determined by your comfort level.

If you see clumping of red blood cells in the tubing or syringe, discard all this material (tubing, syringe and BeneFIX solution) and start again with a new package.

Clumping together of red blood cells in the tubing or syringe has been noticed sometimes when BeneFIX is being given to patients. No side effects have been reported when this clumping has occurred. To minimise the risk of clumping, it is important to limit the amount of blood entering the tubing. Blood should not enter the syringe.

Disposal
Please dispose of all unused solution, empty vials and used needles and syringes into a sharps bin.

Overdose

Immediately contact your doctor, or the Poisons Information Centre (tel: 131 126 in Australia, or tel: 0800 764 766 in New Zealand) if you inject more BeneFIX than your doctor recommends. Do this even if there are no signs of discomfort.

While you are using BeneFIX

Things you must do

- See your doctor immediately if your bleeding does not stop as expected
- Stop the infusion immediately and contact your doctor, if you experience allergic reactions such as skin rash, itching, chest tightness, wheezing, dizziness, hives, faintness, chills, flushing, rapid heartbeat, shortness of breath and/or a swollen face
- Always follow your doctor's instructions carefully
- Tell all the doctors, dentists and pharmacists who are treating you that you are using BeneFIX
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using BeneFIX
- If you become pregnant while you are using BeneFIX, tell your doctor.

Things you must not do

- Do not give BeneFIX to anyone else, even if they have the same condition as you
- Do not use BeneFIX to treat any other complaints unless your doctor tells you to
- Do not stop using BeneFIX or lower the dosage, without checking with your doctor, unless you have an allergic reaction.

Side Effects

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 side effects.

Tell your doctor if you notice any of the following:

- headache
- runny or blocked nose or sneezing
- light-headedness
- fever
- chills
- flushing
- nausea
- vomiting

- diarrhoea
- feeling of tiredness, drowsiness, or lack of energy
- discomfort or swelling at the injection site
- altered taste
- coughing
- burning sensation in the jaw or skull
- changes in your vision
- tremor

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

If any of the following side effects happen, STOP using BeneFIX and tell your doctor immediately:
- a skin rash
- itching
- chest tightness
- wheezing
- dizziness
- hives
- faintness
- rapid heartbeat
- shortness of breath
- a swollen face
- blurred vision.

These side effects could mean that you are having an allergic reaction. These side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using BeneFIX

Storage
Before reconstitution:
Keep BeneFIX in the refrigerator (2˚C to 8˚C). DO NOT freeze.

BeneFIX must be used by the expiry date (Exp) on the label.

If stored at room temperature below 30˚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.

A locked cupboard at least one and a half metres above the ground is a good place to store medicine.

Do not use BeneFIX beyond the date (month and year) printed on the label after the letters Exp, even if it has been stored properly.

Medicines cannot be stored indefinitely.

After Reconstitution:
To stop bacterial contamination of the solution, use the made-up BeneFIX as soon as possible or within 3 hours after reconstitution.

Product Description

What it looks like
BeneFIX comes as a white powder in a glass vial.

Each vial of BeneFIX is provided with a pre-filled diluent syringe containing 0.234% sodium chloride solution and accessories required for making up the solution and injection. These include a sterile infusion set, a sterile vial adapter, sticking plaster, a sterile gauze pad and two (2) alcohol swabs.

Ingredients
Active ingredients: nonacog alfa

Inactive ingredients: glycine, sucrose, L-histidine, polysorbate 80 and sodium chloride solution (0.234%)

Supplier
BeneFIX is supplied in Australia by:

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

WEST RYDE NSW 2114

Toll Free Number: 1800 675 229

BeneFIX is supplied in New Zealand by:

Pfizer New Zealand Limited

PO Box 3998

Auckland

Toll Free Number: 0800 736 363

BeneFIX administration kit is manufactured by Wyeth Farma, Algete, San Sebastian de los Reyes, Madrid, Spain.

Australian Registration Numbers
BeneFIX 250 IU: AUST R 128339
BeneFIX 500 IU: AUST R 128375
BeneFIX 1000 IU: AUST R 128377
BeneFIX 2000 IU: AUST R 128378
BeneFIX 3000 IU: AUST R 203316

Date of preparation
This leaflet was prepared in February 2017.

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INSTRUCTIONS FOR PREPARING AND GIVING AN INJECTION OF BENEFIX

Always use BeneFIX exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will decide the dose of BeneFIX you will receive. This dose and duration will depend on your individual needs for factor IX therapy and upon drug pharmacokinetics (recovery and half-life) that have to be checked regularly. You may notice a difference in the dose you receive if you are changing from a plasma-derived factor IX product to BeneFIX.

Your doctor may decide to change the dose of BeneFIX you receive during your treatment.

Reconstitution and administration

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

BeneFIX is administered by intravenous (IV) injection after reconstitution of the lyophilised powder for injection with the supplied diluent (0.234% w/v sodium chloride solution) in the pre-filled syringe.

Always wash your hands prior to performing the following procedures. Aseptic technique (meaning clean and germ free) should be used during the reconstitution procedure.

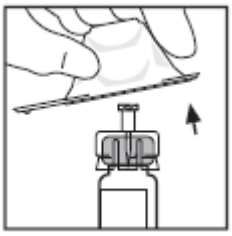
Reconstitution:

1. Allow the vial of lyophilised BeneFIX and the pre-filled diluent syringe to reach room temperature.

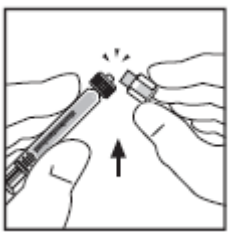
2. Remove the plastic flip-top cap from the BeneFIX vial to expose the central portion of the rubber stopper.

3. Wipe the top of the vial with the alcohol swab provided 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 lid 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.

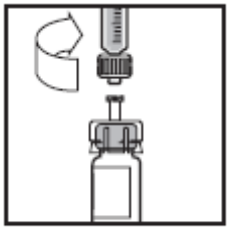
6. Lift the package away from the adapter and discard the package.



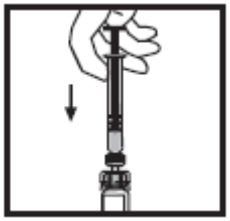
7. Attach the plunger rod to the diluent syringe by pushing and turning firmly.
8. Break off the tamper-resistant plastic tip cap from the diluent syringe by snapping the perforation of the cap. This is done by bending the cap up and down until the perforation is broken. Do not touch the inside of the cap or the syringe tip. The cap may need to be replaced (if not administering reconstituted BeneFIX immediately), so set it aside by placing it on its top.



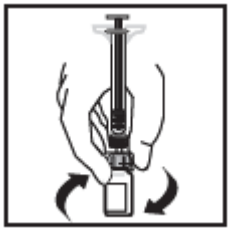
9. Place the vial on a flat surface. Connect the diluent syringe to the vial adapter by inserting the tip of the syringe into the adapter opening while firmly pushing and turning the syringe clockwise until the connection is secured.



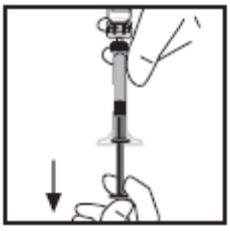
10. Slowly depress the plunger rod to inject all the diluent into the BeneFIX vial.



11. With the syringe still connected to the adapter, gently rotate the vial until the powder is dissolved.



12. <u>The final solution should be inspected visually for particulate matter before administration. The solution should appear clear and colourless.</u>
    Note: If you use more than one vial of BeneFIX per infusion, each vial should be reconstituted as per the previous instructions. The diluent syringe should be removed, leaving the vial adapter in place and a separate large luer lock syringe may be used to draw back the reconstituted contents of each individual vial.
13. Ensuring that the syringe plunger rod is still fully depressed, invert the vial. Slowly draw back all the solution into the syringe.



14. Detach the syringe from the vial adapter by gently pulling and turning the syringe counter-clockwise. Discard the vial with the adapter attached.
    Note: If the solution is not to be used immediately, the syringe cap should be carefully replaced. Do not touch the syringe tip or the inside of the cap.

BeneFIX should be administered immediately or within 3 hours after reconstitution. The reconstituted solution may be stored at room temperature prior to administration.

Administration (Intravenous injection):

BeneFIX should be administered using the pre-filled diluent syringe provided or a single sterile disposable plastic luer lock syringe. In addition, the solution should be withdrawn from the vial using the vial adapter.

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

BeneFIX should be injected intravenously over several minutes. Your doctor may change your recommended infusion rate to make the infusion more comfortable.

If you see clumping of red blood cells in the tubing or syringe, discard all this material (tubing, syringe and BeneFIX solution) and start again with a new package.

Because the use of BeneFIX by continuous infusion has not been evaluated, BeneFIX should not be mixed with infusion solutions or be given in a drip.

Please dispose of all unused solution, empty vials, used needles and syringes in a sharps bin.