

BENEFIX POWDER AND SOLVENT FOR SOLUTION FOR INJECTION

Nonacog alfa (250 IU, 500 IU, 1000 IU or 2000 IU)

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What BeneFIX is used for

BeneFIX is an injectable medicine that is used to help control and prevent bleeding episodes including those people with haemophilia B (a hereditary bleeding disorder caused by a lack of blood clotting factor IX).

BeneFIX is also used to help control and reduce bleeding in surgical settings.

How BeneFIX works

BeneFIX contains active ingredient nonacog alfa (recombinant coagulation factor IX).

People who are born with haemophilia B (also known as Christmas disease) lack sufficient factor IX to control bleeding. BeneFIX works by replacing factor IX to enable their blood to clot.

Before you use BeneFIX

- When you must not use it

Do not take BeneFIX

- If you are hypersensitive (allergic) to nonacog alfa or to any of the other ingredients of the medicine (listed in Product Description).
- If you are allergic to hamster protein.

- Before you start to use it

Tell your doctor, pharmacist or nurse:

- If you have a symptoms or history of allergic reaction like difficulty breathing, shortness of breath, swelling, hives, itching, chills, flushing, tightness of the chest,

wheezing, faintness, low blood pressure and blurred vision.

- If you suffer from liver disease or if you have recently had surgery or you are known to have coagulation disorder, there is an increased risk for blood clotting (coagulation) complications.

Pregnancy and lactation

If you are pregnant, planning for pregnancy or breast-feeding ask your doctor or pharmacist for advice before using this medicine.

During pregnancy and breast-feeding, BeneFIX should only be given if it is clearly indicated.

- Taking other medicines

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

How to use BeneFIX

- How much to use

Refer to **Instructions for Use** for steps to reconstitute the powder for injection.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Dosing for control and prevention of bleeding episode -

In conditions like early bleeding into joint, minor muscle or oral bleeds, the dose of BeneFIX is 20 to 40 IU/dL every 24 hours, for at least 1 day, until the bleeding episode as indicated by pain is resolved or healing is achieved.

In conditions like more extensive

bleeding into joint, muscle bleeding or severe bruising, the dose of BeneFIX is 30 to 60 IU/dL every 24 hours, for 3 to 4 days or more until pain and acute disability are resolved.

In conditions like life-threatening bleeding, the dose of BeneFIX is 60 to 100 IU/dL every 8 to 24 hours until threat is resolved.

Dosing for surgical operation management-

In minor procedures like tooth extraction, the dose of BeneFIX is 30 to 60 IU/dL every 24 hours, for at least 1 day, until healing is achieved.

In major procedures, the dose of BeneFIX is 80 to 100 IU/dL every 8 to 24 hours (before and after surgery), until adequate wound healing, then therapy for at least another 7 days to maintain a factor IX activity of 30% to 60% (IU/dL).

Dosing for long term prevention against bleeding in haemophilia B-

The recommended dose regimen is 100 IU/kg once every week. Children less than 12 years old and younger people may require shorter dosing intervals or a higher doses.

Your doctor will adjust your dosing regimen based on your clinical response.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Use BeneFIX for the duration as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on

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what you should do if you forget to use it.

Administer the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to administer the medicine and skip the missed dose. Do not administer a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using BeneFIX.

Tell your doctor immediately if you become pregnant while using this medication.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give BeneFIX to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

BeneFIX has no influence on the ability to drive or use machines.

side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

Very common side effects:

- headache including migraine and sinus headache;
- cough;
- vomiting;
- fever.

Common side effects:

- factor IX inhibition (may increase risk for severe allergic reaction);
- allergy including swelling of the face or throat, difficulty in speaking and breathing;
- dizziness or altered taste;
- inflammation of the walls of a vein, low blood pressure or flushing;
- nausea;
- rashes and hives;
- pain and tightness of the chest, itchy, redness, pain and discomfort at the infusion site.

Uncommon side effects:

- abnormal heart rate (fast);
- clotting of blood in vessels;
- vision impairment.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of BeneFIX

- Storage

Keep out of the reach and sight of children.

Do not freeze.

Store and transport refrigerated at a temperature of 2°C to 8°C.

When you take BeneFIX out from the refrigerator, you must keep it at a temperature below 30°C for up to 6 months. After this period or the expiry date stated on the carton whichever comes first, BeneFIX should not be used but discarded.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

- White/almost white powder in vial and;
- Clear and colourless solvent for solution for injection in prefilled syringe.

- Ingredients

- Active ingredient
Nonacog alfa (recombinant coagulation factor IX).
- Inactive ingredients
Sucrose, Glycine, L-Histidine, Polysorbate 80, Sodium chloride solution.

Side effects

Like all medicines, BeneFIX can cause

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- MAL numbers:

<u>Product Name</u>	<u>Registration Number</u>
BeneFIX 250 IU powder and solvent for solution for injection	MAL20091920ACZ
BeneFIX 500 IU powder and solvent for solution for injection	MAL20091921AZ
BeneFIX 1000 IU powder and solvent for solution for injection	MAL20091922AZ
BeneFIX 2000 IU powder and solvent for solution for injection	MAL20091923ACZ

Manufacturer

Wyeth Farma S.A., Madrid, Spain.

Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.

Level 10 & 11,

Wisma Averis, Tower 2,

Avenue 5, Bangsar South,

No. 8 Jalan Kerinchi,

59200 Kuala Lumpur, Malaysia

Date of Revision

16/02/2023

Serial Number

NPRA(R3/1)14022023/0238

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Instructions for Use

BENEFIX

[Recombinant Coagulation Factor IX]

Preparation and Reconstitution

The procedures below are provided as guidelines for the reconstitution and administration of BeneFIX. You should follow the specific venipuncture procedures provided by your doctor.

Always wash your hands prior to performing the following procedures. Aseptic technique (clean and germ free) should be used during the reconstitution procedure. All components used in the reconstitution and administration of this product should be used as soon as possible after opening their sterile containers to minimize unnecessary exposure to the atmosphere.

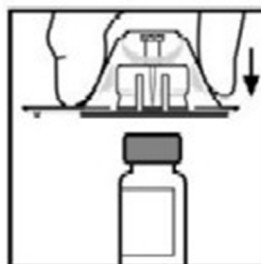
Reconstitution:

Note: BeneFIX will be administered by intravenous infusion (IV) after reconstitution with sterile solvent for injection in the pre-filled syringe.

1. Allow the vial of lyophilised (freeze dried) BeneFIX and the pre filled 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.



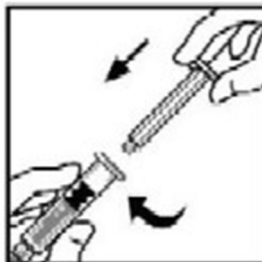
3. Wipe the top of the vial with an alcohol swab provided or use another antiseptic solution and allow to dry. After cleaning do not touch the rubber stopper with your hand or allow it to touch any surface.
4. Peel back the lid from the clear plastic vial adapter package. Do not remove the adapter from 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. Leave the adapter package in place.



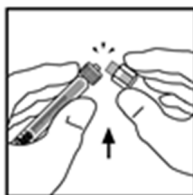
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6. Grasp the plunger rod as shown in the diagram. Avoid contact with the shaft of the plunger rod. Attach the threaded end of the plunger rod to the diluent syringe plunger by pushing and turning firmly.



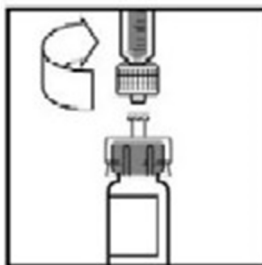
7. Remove the tamper-resistant, plastic-tip cap from the diluent syringe by bending the cap up and down to break the perforation. Do not touch the inside of the cap or the syringe tip. Place the cap on its side on a clean surface in a spot where it would be least likely to become environmentally contaminated.



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



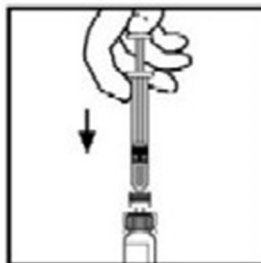
9. Place the vial on a flat surface. Connect the diluent syringe to the vial adapter by inserting the tip into the adapter opening while firmly pushing and turning the syringe clockwise until the connection is secured.



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

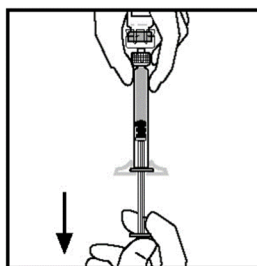


11. Without removing the syringe, gently swirl the contents of the vial until the powder is dissolved.
12. Inspect the final solution for specks before administration. The solution should appear clear and colorless.

Note: If you use more than one vial of BeneFIX per infusion, reconstitute each vial by following the previous instructions.

13. Ensuring that the syringe plunger rod is still fully depressed, invert the vial. Slowly draw the solution into the syringe.

Note: If you prepared more than one vial of BeneFIX, remove the diluent syringe from the vial adapter, leaving the vial adapter attached to the vial. Quickly attach a separate large luer lock syringe and draw back the reconstituted contents 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.



14. Detach the syringe from the vial adapter by gently pulling and turning the syringe counterclockwise. 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 within 3 hours after reconstitution. The reconstituted solution may be stored at room temperature prior to administration.

Infusion of BeneFIX

Your healthcare provider will teach you how to infuse BeneFIX yourself. Once you learn how to do this, you can follow the instructions in this insert.

Before BeneFIX can be infused, you must reconstitute it as instructed above in the **Preparation and Reconstitution** of BeneFIX section.

1. Attach the syringe to the luer end of the infusion set tubing provided.

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2. Apply a tourniquet and prepare the injection site by wiping the skin well with an alcohol swab provided in the kit.



3. Perform venipuncture. Insert the needle on the infusion set tubing into the vein, and remove the tourniquet. The reconstituted BeneFIX product should be injected intravenously over several minutes. The rate of administration should be determined by the patient's comfort level.



Reconstituted BeneFIX should not be administered in the same tubing or container with other medicinal products.

After completion of BeneFIX treatment, remove the infusion set and discard.

BeneFIX should be administered using the infusion set provided in the kit, and the pre-filled diluent syringe provided or a single, sterile, disposable plastic syringe. In addition, the solution should be withdrawn from the vial using the vial adapter.

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

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