

# BeneFIX®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using BeneFIX?

BeneFIX contains the active ingredient nonacog alfa, a coagulation factor IX product. BeneFIX is used to control and treat bleeding and prevent bleeding in people with haemophilia B. People with haemophilia B are deficient in coagulation factor IX.

For more information, see Section [1. Why am I using BeneFIX?](#) in the full CMI.

### 2. What should I know before I use BeneFIX?

Do not use BeneFIX if you have had an allergic reaction to nonacog alfa, hamster proteins or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

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For more information, see Section [2. What should I know before I use BeneFIX?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with BeneFIX and affect how it works. For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use BeneFIX?

- BeneFIX comes in five dosage strengths. Your doctor will prescribe the dosage strength and dose that is right for you.
- BeneFIX is given by injection directly into your veins.
- The BeneFIX powder needs to be reconstituted (made-up) before use. Use only the materials provided in the pack for dissolving the BeneFIX powder with the sodium chloride solution and injecting the made-up BeneFIX solution.
- Your doctor, nurse or pharmacist will show you how to use BeneFIX before you use it for the first time.

More instructions can be found in Section [4. How do I use BeneFIX?](#) in the full CMI.

### 5. What should I know while using BeneFIX?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist</li></ul>
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	<p>you visit that you are using BeneFIX.</p> <ul style="list-style-type: none"> <li>● See your doctor immediately if your bleeding does not stop as expected.</li> <li>● Stop the infusion immediately and contact your doctor if you experience an allergic reaction.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>● Do not stop using this medicine or lower the dose without first checking with your doctor, unless you have an allergic reaction.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>● BeneFIX is not expected to affect your ability to drive or operate machinery.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>● Store BeneFIX in the refrigerator (2°C to 8°C). Do not freeze.</li> <li>● BeneFIX may be stored at room temperature (below 30°C) for a single period up to 6 months. If stored at room temperature it cannot be returned to</li> </ul>

the refrigerator and must be used within 6 months.

- Use the made-up solution of BeneFIX as soon as possible or within 3 hours after reconstitution.

For more information, see Section [5. What should I know while using BeneFIX?](#) in the full CMI.

## **6. Are there any side effects?**

General and administration site side effects have been reported, and are usually mild and temporary. Allergic reactions have been reported for all factor IX products, including BeneFIX. Signs of allergic reactions include a skin rash, itching, chest tightness, wheezing, dizziness, hives, faintness, rapid heartbeat, blurred vision, shortness of breath and/or a swollen face.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# BeneFIX®

**Active ingredient(s):** nonacog alfa (recombinant coagulation factor IX)

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using BeneFIX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using BeneFIX.**

**Where to find information in this leaflet:**

- [1. Why am I using BeneFIX?](#)
- [2. What should I know before I use BeneFIX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use BeneFIX?](#)
- [5. What should I know while using BeneFIX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using BeneFIX?

**BeneFIX contains the active ingredient nonacog alfa.** Nonacog alfa 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

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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.

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 to control and treat bleeding and to prevent bleeding in people with haemophilia B.

## **2. What should I know before I use BeneFIX?**

### **Warnings**

#### **Do not use BeneFIX if:**

- you are allergic to hamster proteins or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

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.

## Check with your doctor if you:

- have liver disease
- are at risk of developing clotting disorders other than haemophilia
- have recently had surgery.

These conditions increase your risk for clotting complications.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. It is not known whether BeneFIX can affect your ability to have children or harm your developing baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether BeneFIX passes into breastmilk.

## 3. What if I am taking other medicines?

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

**Some medicines may interfere with BeneFIX and 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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BeneFIX.**

## **4. How do I use BeneFIX?**

### **How much to use**

- BeneFIX comes in five dosage strengths. Your doctor will prescribe the dosage strength and dose that is right for you. The dose and duration will depend on 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 during your treatment.
- Follow the instructions provided and use BeneFIX until your doctor tells you to stop.

### **How to use BeneFIX**

- 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 in the pack.
- If you do not understand the instructions for injecting BeneFIX found in the pack, ask your doctor or pharmacist for help.
- When you have finished injecting BeneFIX, discard the needle and syringe into a sharps container.

## **How to reconstitute and administer BeneFIX**

- Always wash your hands before doing the following procedures. Use germ-free methods during the make-up (reconstitution) 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 made-up 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 when BeneFIX is 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.

## **If you forget to use BeneFIX**

BeneFIX should be used regularly as agreed with your doctor. If you miss your dose at the usual time, you should inject the next dose as soon as you remember.

**If it is almost time for your next dose, skip the dose you missed and inject your next dose when you are meant to.**

**Do not inject a double dose to make up for the dose you missed.**

## **If you use too much BeneFIX**

If you think that you have used too much BeneFIX, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre  
(**by calling 13 11 26**), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using BeneFIX?**

### **Things you should do**

See your doctor immediately if your bleeding does not stop as expected.

Stop the infusion immediately if you experience an allergic reaction such as skin rash, itching, chest tightness, wheezing, dizziness, hives, faintness, chills, flushing, rapid heartbeat, shortness of breath and/or a swollen face.

### **Call your doctor straight away if you:**

- are using increasing amounts of BeneFIX in order to control a bleed
- experience an allergic reaction.

Remind any doctor, dentist or pharmacist you visit that you are using BeneFIX.

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.

## **Things you should not do**

- Do not stop using this medicine or lower the dosage without first checking with your doctor, unless you have an allergic reaction.
- 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.

## **Driving or using machines**

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

## **Looking after your medicine**

Follow the instructions on the carton on how to take care of your medicine properly.

Keep BeneFIX in the refrigerator (2°C to 8°C). Do not freeze.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

BeneFIX may be stored at room temperature (below 30°C) for a single period up to 6 months. If BeneFIX is stored at room temperature it may not be returned to

refrigerated storage and must be used within 6 months. Write the date on the package when you first store BeneFIX at room temperature.

Do not use this medicine after the expiry date.

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

## **After reconstitution**

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

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Dispose of all unused sodium chloride solution, empty vials, used syringes and needles into a sharps container.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, they are mostly minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Side effects

Side effects	What to do
<ul style="list-style-type: none"><li>● headache</li><li>● runny or blocked nose or sneezing</li><li>● light-headedness</li><li>● fever</li><li>● chills</li><li>● flushing</li><li>● nausea</li><li>● vomiting</li><li>● diarrhoea</li><li>● feeling of tiredness, drowsiness, or lack of energy</li><li>● discomfort or swelling at the injection site</li><li>● altered taste</li><li>● coughing</li><li>● burning sensation in the jaw or skull</li><li>● changes in your vision</li><li>● tremor</li></ul>	<p><b>Speak to your doctor if you have any of these side effects and they worry you.</b></p> <p>These are all mild side effects of BeneFIX injection and will usually disappear on their own. Tell your doctor if they continue.</p>

## Serious side effects

Serious side effects	What to do
<p><b>Allergic reaction:</b></p> <ul style="list-style-type: none"><li>• 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><li>• blurred vision</li></ul>	<p><b>Stop using BeneFIX and call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

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

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side

effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop treatment with any of your medicines.**

## **7. Product details**

This medicine is only available with a doctor's prescription.

### **What BeneFIX contains**

<b>Active ingredient (main ingredient)</b>	nonacog alfa
<b>Other ingredients (inactive ingredients)</b>	glycine, sucrose, histidine, polysorbate 80, sodium chloride solution (0.234%)

**Do not use this medicine if you are allergic to any of these ingredients or hamster proteins.**

### **What BeneFIX 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 plunger rod, a sterile infusion

set, a sterile vial adapter, sticking plaster, a sterile gauze pad and two (2) alcohol swabs.

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

## **Who distributes BeneFIX**

BeneFIX is supplied in Australia by:

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

[www.pfizermedinfo.com.au](http://www.pfizermedinfo.com.au)

BeneFIX is supplied in New Zealand by:

Pfizer New Zealand Limited

PO Box 3998

Auckland

Toll Free Number: 0800 736 363

[www.pfizermedinfo.co.nz](http://www.pfizermedinfo.co.nz)

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

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