

RIXUBIS®

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.

1. Why am I using RIXUBIS?

RIXUBIS contains the active ingredient nonacog gamma (rch), a recombinant coagulation factor IX. RIXUBIS is used to prevent and control bleeding in people with haemophilia B.

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

2. What should I know before I use RIXUBIS?

Do not use if you have ever had an allergic reaction to RIXUBIS 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.

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

3. What if I am taking other medicines?

Some medicines may interfere with RIXUBIS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use RIXUBIS?

- Your doctor will tell you how much medicine to use based on your weight, the severity of your haemophilia B, and where you are bleeding.
- RIXUBIS is given as an injection directly into your veins, usually by yourself, a doctor, nurse, or other trained person.

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

5. What should I know while using RIXUBIS?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using RIXUBIS.• Stop the infusion immediately and contact your doctor if you experience allergic reactions (see side effects).• See your doctor immediately if your bleeding does not stop as expected.• Talk to your healthcare provider before traveling. Plan to bring enough medicine for your treatment during this time.
Looking after your medicine	<ul style="list-style-type: none">• RIXUBIS should be stored below 30°C.

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

6. Are there any side effects?

Some common side effects are stomach-flu-like symptoms, runny nose, sore throat, headache and diarrhoea. Serious side effects may include allergic reactions.

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.

RIXUBIS

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

Consumer Medicine Information (CMI)

This leaflet provides important information about using RIXUBIS. **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 RIXUBIS.**

Where to find information in this leaflet:

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

1. Why am I using RIXUBIS?

RIXUBIS contains the active ingredient nonacog gamma (rch), a recombinant coagulation factor IX.

RIXUBIS 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.

RIXUBIS is used to prevent and control bleeding in people with haemophilia B. People with haemophilia B (Christmas disease) are deficient in coagulation factor IX. RIXUBIS works by replacing factor IX to enable blood to clot. When used regularly (prophylaxis) RIXUBIS can reduce the number of bleeding episodes.

2. What should I know before I use RIXUBIS?

Warnings

Do not use RIXUBIS if:

- you are allergic to nonacog gamma, or any of the ingredients listed at the end of this leaflet.
- you are allergic to hamsters.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have been told that you have inhibitors to factor IX (because RIXUBIS may not work for you).

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 if RIXUBIS may harm your unborn baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if RIXUBIS passes into your milk and if it can harm your baby.

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.

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

4. How do I use RIXUBIS?

How much to use

- Your doctor will tell you how much medicine to use based on your weight, the severity of your haemophilia B, and where you are bleeding.
- You may have to have blood tests done after getting your medicine to be sure that your blood level of factor IX is high enough to clot your blood.
- Follow the instructions provided and use RIXUBIS until your doctor tells you to stop.

When to use RIXUBIS

- RIXUBIS should be used as ordered by your physician.
- Your doctor may give you RIXUBIS when you have surgery.

How to do RIXUBIS infusions

- Your medicine is given as an injection directly into your veins, usually by yourself, a doctor, nurse, or other trained person.
- You should be trained on how to do infusions by your healthcare provider or haemophilia treatment centre. Do not attempt to do an infusion to yourself unless you have been taught how.
- Each vial of RIXUBIS is for single use only, in one patient only. Discard any residue.
- Use only the materials provided in the box for dissolving the RIXUBIS powder and then injecting the RIXUBIS solution** (see step by step instructions for use below).

- **Inject your medicine as soon as possible or within 3 hours after dissolving the powder.**
- **Always wash your hands before doing the following procedures. Use germ-free methods during the making up procedure and during injection.**
- RIXUBIS must not be mixed with other injectable medicines.

Step by step instructions for infusing RIXUBIS

1. Prepare a clean flat surface and gather all the materials you will need for the infusion. Check the expiration date and let the vials with the RIXUBIS concentrate and the water for injections (diluent) warm up to room temperature. Wash your hands and put on clean exam gloves. If infusing yourself at home, the use of gloves is optional.
2. Remove caps from the RIXUBIS concentrate and diluent vials to expose the centres of the rubber stoppers.
3. Disinfect the stoppers with an alcohol swab (or other suitable solution suggested by your healthcare provider or haemophilia centre) by rubbing the stoppers firmly for several seconds and allow them to dry prior to use. Place the vials on a flat surface.
4. Open the BAXJECT II device package by peeling away the lid, without touching the inside of the package.

Do not remove the BAXJECT II device from the package.

5. Turn the package with the BAXJECT II device upside down and place it over the top of the diluent vial. Fully insert the clear plastic spike of the device into the centre of the diluent vial's stopper by pushing straight down. Grip the package at its edge and lift it off the device. Be careful not to touch the white plastic spike.

Do not remove the blue cap from the BAXJECT II device.

The diluent vial now has the BAXJECT II device connected to it and is ready to be connected to the RIXUBIS vial.

6. To connect the diluent vial to the RIXUBIS vial, turn the diluent vial over and place it on top of the vial containing RIXUBIS concentrate. Fully insert the white plastic spike into the RIXUBIS vial's stopper by pushing straight down. Diluent will flow into the RIXUBIS vial. This should be done right away to keep the liquid free of germs.
7. Swirl the connected vials gently and continuously until the RIXUBIS is completely dissolved. **Do not shake.**

The RIXUBIS solution should look clear and colourless. If not, do not use it and notify Baxter immediately.

8. Take off the blue cap from the BAXJECT II device and connect the syringe by screwing the syringe clockwise into the BAXJECT II device.

Be careful to not inject air.

9. Turn over the connected vials so that the RIXUBIS vial is on top. Draw the RIXUBIS solution into the syringe

by pulling back the plunger slowly. Disconnect the syringe from the vials.

10. If you are using more than one vial of RIXUBIS, the contents of more than one vial may be drawn into the same syringe.

Make sure you mix each vial of RIXUBIS with the water for injections that is provided in the box (Following Steps 1-9).

You will need a separate BAXJECT II device to mix each additional vial of RIXUBIS.

11. Attach the infusion needle to the syringe using a winged (butterfly) infusion set, if available. Point the needle up and remove any air bubbles by gently tapping the syringe with your finger and slowly and carefully pushing air out of the syringe and needle.
12. Apply a tourniquet and get the infusion site ready by wiping the skin well with an alcohol swab (or other suitable solution suggested by your healthcare provider or haemophilia centre).
13. Insert the needle into the vein and remove the tourniquet. Slowly infuse the RIXUBIS.

Do not infuse any faster than 10 mL per minute.

14. Take the needle out of the vein and use sterile gauze to put pressure on the infusion site for several minutes.

Do not recap the needle. Place it with the used syringe in a hard-walled Sharps container for proper disposal.

15. Dispose of the used vials and BAXJECT II system in your hard-walled Sharps container without taking them apart. Do not dispose of these supplies in ordinary household trash.
16. Remove the peel-off label from the RIXUBIS vial and place it in your logbook. Clean any spilled blood with a freshly prepared mixture of 1 part bleach and 9 parts water, soap and water, or any household disinfecting solution.

Important: Contact your healthcare provider or local haemophilia treatment centre if you experience any problems.

If you forget to use RIXUBIS

If you miss your dose at the usual time, proceed with the next administration immediately, and continue at regular intervals as advised by your doctor.

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

If you use too much RIXUBIS

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

You should immediately:

- phone the National Poisons Centre (telephone **0800 POISON** or **0800 764766**), 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 RIXUBIS?

Things you should do

- Stop the infusion immediately and contact your doctor if you experience allergic reactions (see side effects)

Talk to your healthcare provider before travelling. Plan to bring enough medicine for your treatment during this time. It is important to obtain a written statement from your physician, explaining the reasons why you need to have this medicine and injecting devices with you, otherwise you may not be allowed to bring it into the country of travelling. Please ensure you have multiple copies of the letter if you travel to more than one country.

Call your doctor straight away if:

- your bleeding does not stop as expected.

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

Things you should not do

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how RIXUBIS affects you.

Looking after your medicine

- RIXUBIS should be stored below 30°C for the duration of its shelf life.
- Store in the original package in order to protect from light.

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

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 windowsills.

Keep it where young children cannot reach it.

When to discard your medicine

RIXUBIS contains no preservatives. Reconstituted product (what you get after dissolving the powder with the sterile

water) must be used within 3 hours and cannot be stored or refrigerated.

Discard any medicine left in the vial at the end of your infusion.

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.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are 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.

Less serious side effects

Less serious side effects	What to do
<p>Stomach-flu-like symptoms:</p> <ul style="list-style-type: none"> • nausea • vomiting • stomach pain <p>Other common side effects:</p> <ul style="list-style-type: none"> • runny nose • sore throat • headache • diarrhoea 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Allergic reactions:</p> <ul style="list-style-type: none"> • rash or hives • itching • tightness of the throat • chest pain or tightness • difficulty breathing, shortness of breath • wheezing • light-headedness, dizziness • nausea • faintness • chills, flushing • rapid heartbeat • swollen face 	<p>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.</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.

Reporting side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit-risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions at <https://pophealth.my.site.com/carmreportnz/s/>

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

7. Product details

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

What RIXUBIS contains

Active ingredient (main ingredient)	nonacog gamma
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Histidine• sodium chloride• calcium chloride dihydrate• mannitol• sucrose• polysorbate 80

Do not take this medicine if you are allergic to any of these ingredients.

What RIXUBIS looks like

RIXUBIS comes as a white or off-white powder in a glass vial.

Each vial of your medicine is accompanied by a glass vial containing water for injections for dissolving the powder.

The package also comes with a device known as the BAXJECT II which is used to transfer the sterile water in the glass vial to the powder vial.

An ancillary set containing alcohol swabs, adhesive bandages, an infusion set, a syringe and a butterfly needle may be supplied with your medicine.

RIXUBIS is available in five strengths:

- 250 IU
- 500 IU
- 1000 IU
- 2000 IU
- 3000 IU

Not all strengths may be marketed.

Who distributes RIXUBIS

RIXUBIS is supplied in New Zealand by:

Takeda New Zealand Limited
Level 10, 21 Queen Street
Auckland 1010
New Zealand

Telephone: 0508 169 077

<https://www.takeda.com/en-nz/>

This leaflet was prepared in February 2026.

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