RIXUBIS®

nonacog gamma (rch) (recombinant coagulation factor IX), 250, 500, 1000, 2000, 3000 IU /vial

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about RIXUBIS. It does not contain all of the available information. All medicines have risks and benefits. Your doctor has weighed the risks of using your medicine against the benefit that it will have for you.

It does not take the place of talking to your doctor or pharmacist.

If you have any concerns about having this medicine, ask your doctor or pharmacist.

Please read this leaflet carefully before using your medicine as it contains information about your medicine.

Keep this leaflet with your medicine.

You may need to read it again.

What RIXUBIS is

RIXUBIS, nonacog gamma (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 RIXUBIS is used for

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

Your medicine is used to prevent and control bleeding in people with haemophilia B.

Your doctor may give you RIXUBIS when you have surgery.

Your medicine can reduce the number of bleeding episodes when used regularly (prophylaxis).

Before you use RIXUBIS

To make sure that your medicine is suitable for you, it is important to tell your doctor or pharmacist if any of the points below apply to you. If there is anything you do not understand, ask your doctor or pharmacist to explain.

Do not use RIXUBIS if you:

- are allergic to hamsters.
- are allergic to any ingredients in RIXUBIS (see "What is in RIXUBIS?").

What should I tell my doctor before using RIXUBIS?

You should tell your doctor if you:

- have or have had any medical problems.
- take any medicines, including prescription and non-prescription medicines, such as over-the-counter medicines, supplements or herbal remedies.
- have any allergies, including allergies to hamsters.
- are breastfeeding. It is not known if RIXUBIS passes into your milk and if it can harm your baby.
- are pregnant or planning to become pregnant. It is not known if RIXUBIS may harm your unborn baby.
- have been told that you have inhibitors to factor IX (because RIXUBIS may not work for you).

How RIXUBIS is given

- Your medicine is given as an injection directly into your veins, usually by yourself, a doctor, nurse, or other trained person.
- Your medicine contains no additives that would prevent the growth of bacteria once the powder is dissolved with sterile water. For this reason, each vial of RIXUBIS is for single use only, in one patient only. Discard any residue.
- Your medicine should be administered as ordered by your physician. You should be trained on how to do infusions by your healthcare provider or haemophilia treatment centre. Many people with haemophilia B learn to infuse their medicine by themselves or with the help of a family member.
- 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.

Use only the materials provided in the box for dissolving the RIXUBIS powder and then injecting the RIXUBIS solution (see INSTRUCTIONS FOR USE).

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.

If you miss/forget your injection

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 the forgotten dose.

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 medicine than your doctor recommends. Do this even if there are no signs of discomfort.

While you are using RIXUBIS

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 discomfort, 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 RIXUBIS
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using RIXUBIS
- If you become pregnant while you are using your medicine, tell your doctor.
- Talk to your healthcare provider before traveling. 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 travelling to more than one country.

Things you must 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.

Side effects

Allergic reactions may occur with your medicine.

Call your doctor or get emergency treatment right away if you get a rash or hives, itching, tightness of the throat, chest pain or tightness, difficulty breathing, lightheadedness, dizziness, nausea or fainting.

Some common side effects of RIXUBIS are stomach-flu-like symptoms (such as nausea, vomiting and stomach pain), runny nose, sore throat, headache and diarrhoea.

Tell your doctor or pharmacist about any side effects that bother you or do not go away.

These are not all the possible side effects with your medicine. You can ask your doctor or pharmacist for information that is written for healthcare professionals.

After using RIXUBIS

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.

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.

Keep out of the reach and sight of children.

Do not use RIXUBIS after the expiry date which is printed on the label after the word 'EXP'.

The expiry date refers to the last day of that month.

Dispose of all materials, including any leftover reconstituted medicine, in an appropriate container.

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.

Instructions for use

Do not attempt to do an infusion to yourself unless you have been taught how by your healthcare provider or haemophilia center.

Always follow the specific instructions given by your healthcare provider. The steps listed below are general guidelines for using your medicine. If you are unsure of the procedures, please call your healthcare provider before using.

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 centers of the rubber stoppers.
3. Disinfect the stoppers with an alcohol swab (or other suitable solution suggested by your healthcare provider or haemophilia center) 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 center 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 colorless. 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 center).
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 center if you experience any problems.

Product Description

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.

What is in RIXUBIS?

The active substance in RIXUBIS is nonacog gamma. Five strengths, i.e. 250 IU, 500 IU, 1000 IU, 2000 IU and 3000 IU of RIXUBIS are commercially available.

Inactive ingredients: histidine, sodium chloride, calcium chloride dihydrate, mannitol, sucrose, polysorbate 80.

Supplier

RIXUBIS is supplied in Australia by:

Takeda Pharmaceuticals Australia Pty Ltd

Level 39, 225 George Street

Sydney NSW 2000

Australia

Telephone: 1800 012 612

www.takeda.com/eu-au

RIXUBIS is supplied in New Zealand by:

Takeda New Zealand Limited

Level 10, 21 Queen Street

Auckland 1010

New Zealand

Telephone: 0508 169 077

www.takeda.com/en-au

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