

## Consumer Medicine Information

### What is in this leaflet

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

All medicines have risks and benefits. Your doctor has weighed the risks of you using NeoRecormon against the benefits they expect it will have for you.

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

**Keep this leaflet with the medicine.**

You may need to read it again.

### What NeoRecormon is used for

NeoRecormon is used to treat anaemia caused by chronic kidney disease.

Anaemia is caused by a lack of red blood cells or haemoglobin which transport oxygen in the blood. If you have anaemia, your body's tissues might not receive enough oxygen. Symptoms may include tiredness, weakness and shortness of breath.

NeoRecormon may also be used:

- If you are planning to have major surgery and you are going to have your own blood collected for use during the surgery.
- To prevent anaemia in premature babies.
- If you have anaemia after being treated with chemotherapy for cancer and you can't have a blood transfusion. In some studies, people with cancer treated with medicines like NeoRecormon for anaemia did not live as long as people not receiving these medicines.

NeoRecormon contains the active ingredient epoetin beta (pronounced ee-poe-tin bee-ta). Epoetin beta is also known as recombinant human erythropoietin (pronounced ee-rithroe-poy-tin).

NeoRecormon belongs to a group of medicines known as hormones. The kidneys produce the natural hormone erythropoietin, which stimulates the production of red blood cells in the bone marrow and spleen.

Like erythropoietin, NeoRecormon works by increasing the number of red blood cells and the haemoglobin level in your blood.

Your doctor, however, may have prescribed NeoRecormon for another reason.

**Ask your doctor if you have any questions about why NeoRecormon has been prescribed for you.**

NeoRecormon is not addictive.

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

### Before you use NeoRecormon

#### When you must not use it

**Do not use NeoRecormon if:**

- **You have had an allergic reaction to epoetin beta or any ingredients listed at the end of this leaflet.** Symptoms of an allergic reaction include swelling, itching, rash or breathing difficulties.
- **You have high blood pressure that is not well controlled.**

- **You or your baby has phenylketonuria (a genetic metabolic disease).** NeoRecormon contains phenylalanine as an inactive ingredient and you should consult your doctor about the risks.
- **You are donating your own blood before surgery, and:**
  - **you have had a heart attack or stroke in the month before your treatment, or**
  - **you have new or increasing chest pain, or**
  - **you are at risk of blood clots in the veins (deep vein thrombosis) or if you have had clots before.****If any of these apply or might apply to you, tell your doctor at once.**
- **The package is torn or shows signs of tampering.**
- **The expiry date (EXP) printed on the pack has passed.** If you use this medicine after the expiry date has passed it may have no effect at all, or worse, may have an unexpected effect.

**If you are not sure if you should be using NeoRecormon, talk to your doctor.**

#### Use in children

NeoRecormon may be used to treat anaemia due to kidney disease in children who are at least 2 years of age.

NeoRecormon is also approved for treating anaemia in premature babies born before 34 weeks and weighing between 750 and 1500 grams.

#### Before you start to use it

Your doctor must know about all the following before you start to use NeoRecormon.

**Tell your doctor if:**

- **You are allergic to any other medicines, foods, dyes or preservatives.**
- **You have any other health problems especially the following:**
  - blood clotting diseases
  - high blood pressure - it is important to follow all your doctor's instructions to control your blood pressure, including any changes to your diet
  - cancer
  - epilepsy
  - excess levels of aluminium in the blood as a result of kidney disease treatment
  - folic acid or vitamin B12 deficiencies
  - you have had problems with another erythropoietin-type medicine
  - liver disease
  - any other illness or health problems.
- **You are using NeoRecormon for donating your own blood before surgery and you weigh less than 50kg.**
- **You are pregnant or plan to become pregnant.** NeoRecormon is not generally recommended for use in pregnant women unless the benefits of treatment outweigh the risks to the unborn baby.
- **You are breast-feeding or plan to breast-feed.** Because epoetin beta occurs naturally in

the body, it has not been possible to determine whether NeoRecormon passes into the breast milk following injection. Your doctor will discuss the risks and benefits of using NeoRecormon if you are breast-feeding.

#### Do not misuse NeoRecormon.

Misuse by healthy people may lead to an excessive increase in the number of red blood cells in the blood. Such an increase may cause life-threatening effects on the heart and blood vessels.

#### Taking other medicines

**Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or health food shop.**

Some medicines may interfere with NeoRecormon and may affect how well it works. Your doctor or pharmacist may have more information on medicines to be careful with or avoid while taking NeoRecormon.

**Ask your doctor or pharmacist if you are not sure about any medicine.**

### How to use NeoRecormon

NeoRecormon can be given by your doctor or nurse. Alternatively your doctor, nurse or pharmacist may teach you or your carer how to inject NeoRecormon. Do not inject yourself with NeoRecormon unless you have received training.

**Follow all directions given to you by your doctor, nurse or pharmacist carefully.**

Those directions may differ from the information contained in this leaflet.

A NeoRecormon patient support kit is available. For more information contact your doctor, healthcare professional or Roche Medical Information service on 1800 233 950 (Australia) or 0800 656 464 (New Zealand).

#### How much to inject

The dosage of NeoRecormon is expressed in international units (IU). Your doctor will tell you how much and how often to inject NeoRecormon according to your individual needs.

If necessary, depending on your response to treatment, your dose may be changed by your doctor.

Your doctor will keep track of your response to NeoRecormon by asking questions and doing tests such as taking your blood pressure or taking blood.

**Do not exceed or change the dose recommended by your doctor.**

#### How to inject it

NeoRecormon can be administered by subcutaneous (under the skin) or intravenous (into the vein) injection. Your doctor will decide which way is right for you.

#### Intravenous administration

Only a health professional should administer NeoRecormon intravenously.

#### Subcutaneous administration

It is recommended that the first dose of NeoRecormon be administered by a doctor or nurse.

Your doctor may discuss whether it would be more convenient for you to receive your

injections at home, in which case you or a family member would be instructed on how to give the injection properly. This is a simple procedure and many patients prefer it.

If your doctor has directed you to use NeoRecormon by subcutaneous injection, please follow the instructions below.

You should read these directions from beginning to end before starting your injection. Follow these instructions carefully. Consult your doctor if you require further instructions.

**Remember that cleanliness is vital so be sure to wash your hands!**

#### **Preparing to self-inject**

##### **Before you begin**

1. Find a clean, comfortable area.
2. Gather all the medicinal supplies you will need:
  - an alcohol swab.
  - some cotton wool or a dry sterile pad.
  - a sharps disposal bin.
3. Remove the NeoRecormon pre-filled syringe from the fridge. Leave it out of the fridge for 30 minutes before use or gently warm the syringe in the palms of your hands for about 1 minute. Be careful not to shake it.
4. Check the expiry date (EXP). Do not use NeoRecormon after the expiry date shown on the pre-filled syringe label.
5. Check that the liquid has no discolouration, cloudiness or particles. The liquid should look clear and colourless.

##### **Preparing the syringe and needle**

6. Wash your hands thoroughly.
7. Remove the protective covering from the needle packaging.
8. Remove the rubber cap from the end of the syringe.
9. Push the needle firmly onto the syringe while gently twisting.
10. Pull the needle shield straight off the needle.
11. If you notice any air bubbles in the syringe, hold the syringe with the needle facing upwards, lightly tap the syringe to bring the air bubbles to the top. You may need to gently push the plunger in slightly to push air out of the syringe.
12. Check the dose of medication your doctor has prescribed. You may need to gently push the plunger to push out some medication to get the dose your doctor has prescribed.
13. If you need to put the syringe (with the needle attached) down, make sure the plastic guard covers the needle and place on a clean flat surface.
14. The syringe is now ready for use.

##### **Choosing the injection site**

15. Choose an injection site in your stomach area or the top of your thigh.
16. Avoid your navel and waistline.
17. Change injection sites with each injection to prevent soreness in one spot.
18. Never inject into a red or swollen area.
19. Never inject NeoRecormon into a muscle.

##### **Preparing the injection site**

20. Clean the injection site with an alcohol swab and let the skin dry (10 seconds).

21. Remove the protective needle guard from the end of the syringe and hold the syringe with the needle facing upwards.
22. Grab your skin at the injection site firmly between your thumb and forefinger to elevate your skin.

##### **Injecting the medicine**

23. Hold the syringe at a 45 degree angle to your skin.
24. Insert the needle in one quick motion with the bevel (flat edge) facing upwards.
25. Slowly push the plunger all the way down.
26. Once all the liquid has left the syringe, pull out the needle at the same angle at which you put it in.
27. Do not recap the needle.
28. If you notice slight bleeding, gently press over the injection site with some cotton wool or a dry sterile pad.

Remember: Most people can learn to give themselves a subcutaneous injection, but if you experience difficulty, please do not be afraid to ask for help and advice from your doctor, nurse or pharmacist.

##### **Cleaning up after your injection**

29. The needle and syringe must be used ONCE only.
30. Dispose of the needle and syringe into a sharps container immediately after injection.
31. Do not replace the needle cover.
32. NEVER place used needles and syringes into your normal household waste bin.  
If you are not sure how to dispose of the needles and syringes, consult your doctor, nurse or pharmacist on how to properly dispose of the syringes and needles.

##### **When to inject NeoRecormon**

Your doctor will tell you how often to use this medicine.

Injecting NeoRecormon at the same time of the day will have the best effect. It will also help you remember your injections.

**Follow your doctor's instructions exactly on when to inject NeoRecormon.**

##### **How long to use NeoRecormon**

Your treatment period could range from a few weeks up to a lifetime, depending on your illness.

**Continue using NeoRecormon until your doctor tells you to stop.**

Your doctor will decide when your treatment should be stopped. It is important to keep using NeoRecormon even if you feel well.

##### **If you forget to use NeoRecormon**

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

**Otherwise, inject it as soon as you remember, and then go back to using NeoRecormon as you would normally.**

**Do not have a double dose to make up for the injection that you missed.**

Because NeoRecormon is administered over prolonged periods, occasional missed doses are not expected to have a significant effect on your treatment.

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.**

*If you use too much NeoRecormon (overdose)*

**Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26 in Australia or 0800 764 766 [0800 POISON] in New Zealand) for advice or go to your nearest Accident and Emergency if you think that you or anyone else may have used too much NeoRecormon. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

**Keep these telephone numbers handy.**

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#### **While you are using NeoRecormon**

##### *Things you must do*

**Use NeoRecormon exactly as your doctor has prescribed.**

**Tell all doctors, dentists and pharmacists who are treating you that you are using NeoRecormon.**

**Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or pharmacist that you are using NeoRecormon.**

If you have blood pressure problems, it is important to follow all your doctor's instructions to control your blood pressure, including any changes to your diet, while using NeoRecormon.

Most people's blood iron levels decrease when using NeoRecormon. Almost all patients will need to be treated with iron supplements.

**Tell your doctor if you become pregnant while using NeoRecormon.**

**Tell your doctor if, for any reason, you have not used NeoRecormon exactly as prescribed.**

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

**Be sure to keep all of your appointments with your doctor so that your progress can be checked.**

Your doctor will keep track of your response to NeoRecormon by asking questions and doing tests such as taking your blood pressure or taking blood.

##### *Things you must not do*

**Do not stop using NeoRecormon or change the dose without first checking with your doctor.**

**Do not let yourself run out of medicine over the weekend or on holidays.**

**Do not give NeoRecormon to anyone else even if they have the same condition as you.**

**Do not use NeoRecormon to treat other complaints unless your doctor says to.**

**Do not switch to any other brands of epoetin without consulting your doctor.**

##### *Things to be careful of*

**Be careful driving or operating machinery until you know how NeoRecormon affects you.**

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

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## Side effects

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using NeoRecormon.**

NeoRecormon helps most people with anaemia but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor if you notice any of the following and they worry you:**

- feeling tired or lacking energy, looking pale; this may be due to changes in your blood iron levels. Your doctor may prescribe an iron supplement for you
- headache
- bleeding or bruising more easily
- swelling of the arms, feet or legs
- stinging or swelling around the injection area
- chest or throat infection, difficulty breathing, cough
- weakness
- nausea and vomiting
- pain with urination or increased urgency and/or frequency of urination.

**Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital, if you notice the following:**

- stabbing, migraine-like headache
- cardiac (heart) symptoms such as chest pain, shortness of breath, double vision, dizziness, feeling lightheaded or tingling of extremities (fingers and toes)
- swelling, pain, tenderness, warmth or discolouration of one leg or arm or along a vein in your leg or arm
- sudden shortness of breath, chest pain, palpitations or coughing up blood
- sudden trouble walking, speaking, seeing or understanding what someone is saying
- sudden onset of wheezing or difficulty breathing, swollen tongue, face or throat
- severe skin reactions, hives, blisters or rash that may cover your whole body  
A severe allergic reaction (very rare) can occur, especially just after an injection. This must be treated at once.

You may experience flu-like symptoms (very rare) particularly when starting treatment. These include fever, chills, headaches, pain in the limbs, bone pain and/or generally feeling unwell. These reactions are usually mild to moderate and go away within a few hours or days.

This is not a complete list of all possible side effects. Your doctor or pharmacist has a more complete list. Other side effects may occur in some people and there may be some not yet known.

**Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on the above list.**

**Ask your doctor or pharmacist if you don't understand anything in this list.**

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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## After using NeoRecormon

### Storage

**Store NeoRecormon pre-filled syringes in the fridge at 2 to 8°C. Do not freeze.**

**Always keep NeoRecormon in its carton, in the fridge, until it is time to use it.**

This will protect NeoRecormon from being affected by light. If you take the pre-filled syringes out of the pack they may not keep well.

You can use NeoRecormon if it has been left out of the fridge for no longer than 3 days (a single period only) at room temperature (up to 25°C).

**Do not store NeoRecormon or any other medicine in a bathroom or near a sink or any other place where there is high humidity.**

**Do not leave NeoRecormon in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep NeoRecormon where young children cannot reach it.**

An appropriate container on the top shelf of a fridge is a good place to store NeoRecormon.

### Disposal

The syringe is intended for single use ONLY and must be thrown away after the injection. Dispose of the syringe with the needle in a puncture proof container as instructed by your doctor, nurse or pharmacist.

Never put the used syringe/needle in your normal household garbage.

**If your doctor tells you to stop using NeoRecormon, or the pre-filled syringe has passed its expiry date, ask your pharmacist what to do with any pre-filled syringes that are left over.**

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## Product description

### Availability

NeoRecormon pre-filled syringes are available in the following strengths (syringe plungers and packaging are coloured as indicated below to easily identify the strength):

- 2000 IU/0.3 mL (orange)
- 3000 IU/0.3 mL (blue)
- 4000 IU/0.3 mL (red)
- 5000 IU/0.3 mL (grey)
- 6000 IU/0.3 mL (green)
- 10000 IU/0.6 mL (purple)

Each pre-filled syringe contains 6 pre-filled syringes containing solution for injection and 6 needles.

### What NeoRecormon pre-filled syringes look like

NeoRecormon solution for injection is contained in a disposable glass syringe. The solution is clear and colourless.

A stainless steel needle is also supplied with the syringe to allow for subcutaneous injection.

### Ingredients

#### Active ingredient

- epoetin beta (recombinant human erythropoietin)

#### Inactive ingredients

Each pre-filled syringe also contains:

- urea

- sodium chloride
- monobasic sodium phosphate
- dibasic sodium phosphate
- calcium chloride
- polysorbate 20
- glycine
- leucine
- isoleucine
- threonine
- glutamic acid
- phenylalanine

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## Distributor

### Distributed in Australia by:

Roche Products Pty Limited  
ABN 70 000 132 865  
Level 8, 30 Hickson Road  
Sydney NSW 2000  
AUSTRALIA

Medical enquiries:

1800 233 950

### Distributed in NZ by:

Roche Products (New Zealand) Limited  
PO Box 109113 Newmarket  
Auckland 1149  
NEW ZEALAND

Medical enquiries:

0800 276 243

Please check with your pharmacist for the latest Consumer Medicine Information.

### Australian Registration Numbers:

2000 IU/0.3 mL: AUST R 104262  
3000 IU/0.3 mL: AUST R 104263  
4000 IU/0.3 mL: AUST R 104264  
5000 IU/0.3 mL: AUST R 104265  
6000 IU/0.3 mL: AUST R 104266  
10000 IU/0.6 mL: AUST R 104267

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