

## 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.

**WARNING:** Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

### 1. Why am I using NeoRecormon?

NeoRecormon contains the active ingredient *epoetin beta*. 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.

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

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

Do not use if you have ever had an allergic reaction to NeoRecormon 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 NeoRecormon?](#) in the full CMI.

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

Some medicines may interfere with NeoRecormon 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 NeoRecormon?

- Your doctor will tell you how much and how often to inject NeoRecormon according to your individual needs.
- 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.

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

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

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using NeoRecormon.</li><li>• 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.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly</li><li>• Do not let yourself run out of medicine over the weekend or on holidays.</li><li>• Do not switch to any other brands of epoetin without consulting your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• 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.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store NeoRecormon pre- filled syringes in the fridge at 2 to 8 °C. Do not freeze. Keep NeoRecormon in its carton, in the fridge, until it is time to use it.</li><li>• 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).</li></ul>

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

### 6. Are there any side effects?

When you are using NeoRecormon, you can have some serious side effects. Serious side effects include: stabbing, migraine-like headache, chest pain, shortness of breath, double vision, dizziness, feeling lightheaded or tingling of extremities, 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.

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.

**WARNING FOR CANCER PATIENTS: use of medicines such as NeoRecormon which stimulate red blood cell production for anaemia in patients with cancer has been associated with increased risk of death in some studies. Your doctor should only use NeoRecormon to treat your anaemia if it is caused by chemotherapy and only when blood transfusion is not an appropriate treatment option.**

# NeoRecormon®

Active ingredient: *epoetin beta* [recombinant human erythropoietin]

## Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

### [NeoRecormon®](#)

1. Why am I using NeoRecormon?
2. What should I know before I use NeoRecormon?
3. What if I am taking other medicines?
4. How do I use NeoRecormon?
5. What should I know while using NeoRecormon?
6. Are there any side effects?

### [NeoRecormon®](#)

1. Why am I using NeoRecormon?
2. What should I know before I use NeoRecormon?

#### Warnings

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Check with your doctor if you:

Pregnancy and breastfeeding

Use in children

3. What if I am taking other medicines?
4. How do I use NeoRecormon?

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## 1. Why am I using NeoRecormon?

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

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

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.

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

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

### Warnings

Do not use NeoRecormon if:

- you are allergic to NeoRecormon, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have high blood pressure that is not well controlled.
- 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.

**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.

Check with your doctor if you:

- take any medicines for any other condition
- **have or have had any other health problems especially the following:**
  - blood clotting conditions such as heart attack or deep vein thrombosis
  - bleeding conditions including stroke
  - cancer
  - epilepsy
  - you have had problems with another erythropoietin-type medicine
  - liver disease
  - you or your baby has severe phenylketonuria (a genetic metabolic disease). NeoRecormon contains phenylalanine as an inactive ingredient and you should consult your doctor about the risks.
  - you have been diagnosed with Pure Red Cell Aplasia (your bone marrow cannot produce enough red blood cells)
  - you had a severe cutaneous adverse reaction (serious skin reaction) after previous treatment with an erythropoietin product, include NeoRecormon
  - any other illness or health problems.
- **are using NeoRecormon for donating your own blood before surgery and you weigh less than 50 kg.**

If you have high blood pressure - it is important to follow all your doctor's instructions to control your blood pressure, including any changes to your diet. Contact your doctor immediately or go to the nearest emergency centre if you get a sudden stabbing migraine headache as

this can mean your blood pressure is very high and you could need urgent medical attention.

If NeoRecormon does not work properly or if you have abnormal blood test results, your doctor may decide to perform further testing. Your doctor might adjust or tell you to stop using this medicine

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Your doctor will discuss the risks and benefits of using NeoRecormon if you are breast-feeding.

### Use in children

- NeoRecormon should not be used in infants (below 2 years of age) or in children who have certain conditions. Your doctor will determine whether NeoRecormon is appropriate and what the starting dose should be.

## 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.

## 4. How do I use NeoRecormon?

### When and how much to use

- 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. The recommended subcutaneous starting dose is 60 IU/kg/week and the maximum dose is 1200 IU/kg/week.
- 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.**
- Your treatment period could range from a few weeks up to a lifetime, depending on your illness.
- 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 to inject NeoRecormon

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.

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.

### 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.

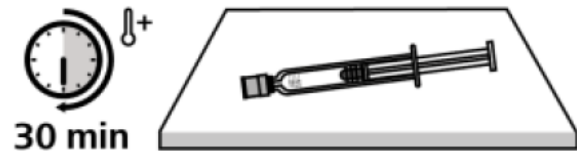
You should read these directions from beginning to end before starting your injection. Follow these instructions carefully. Consult your doctor if you require further instructions.

### Preparing to self-inject

Before you begin

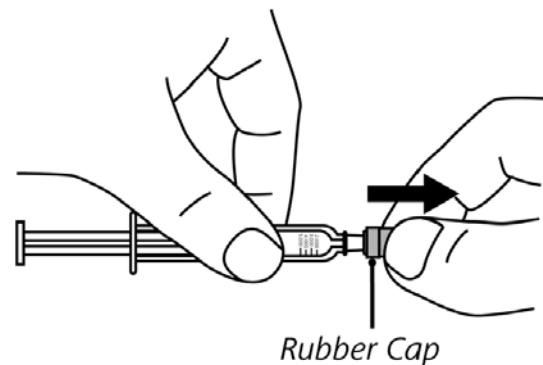
1. Find a clean, comfortable area.
2. Gather all the medicinal supplies you will need:
  - an alcohol swab.
  - some cotton wool or a dry sterile pad.
  - a sharps disposal bin.
3. Take the carton with the syringe and needle out of the fridge and check that the carton has not been damaged and the expiry date (EXP) has not passed. **Do not** use if the expiration date has passed or if the carton appears tampered with.
4. Inspect the syringe and needle closely. Check that the liquid has no discolouration, cloudiness or particles. The liquid should look clear and colourless. Do not use the syringe if the liquid is cloudy, discoloured or has particles.
5. Leave the syringe out of the fridge on a clean flat surface for 30 minutes so it can warm up on its own to room temperature before use. Leave the needle cap on while it warms up.
  - If the syringe does not reach room temperature, this could cause the injection to feel uncomfortable and make it hard to push the plunger.

- **Do not** speed up the warming process in any way, and **do not** put the syringe in a microwave or in warm water.

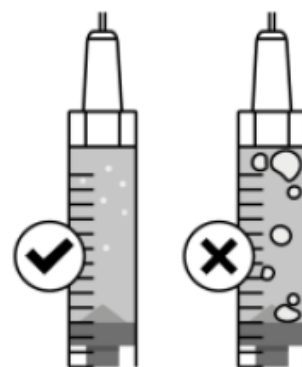


### Preparing the syringe and needle

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.



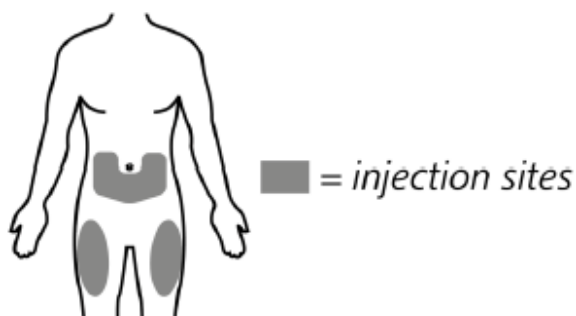
9. Push the needle firmly onto the syringe while gently twisting.
10. Pull the needle shield straight off the needle.
11. If you notice any air bubbles in the syringe, hold the syringe with the needle facing upwards, lightly tap the syringe to bring the air bubbles to the top. You may need to gently 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 the lower part of your stomach area below the belly button or the top of your thigh.



16. Do not inject within a 5 cm area directly around your belly button
17. Change injection sites with each injection to prevent soreness in one spot.
18. Never inject into moles, scars, bruises or areas where the skin is tender, red, hard, swollen or not in tact
19. Never inject NeoRecormon into a muscle or vein.

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

20. Clean the injection site with an alcohol swab and let the skin dry (10 seconds). **Do not** fan, blow on or touch the cleaned area before giving the injection



21. Remove the protective needle guard from the end of the syringe and hold the syringe with the needle facing upwards. Use the syringe within 5 minutes of removing the cap; otherwise, the needle may clog.
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 to 90 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. **Do not** rub the injection site.

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.

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

NeoRecormon should be used regularly at the same time of each dosing day. **If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose 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**

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

**You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26) for Australia and National Poisons Centre (by calling 0800 764 766) for New Zealand, 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 NeoRecormon?**

**Things you should 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.

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

- have a sudden, migraine-like headache
- have a severe skin reaction

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

**Things you should 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.**

**Driving or using machines**

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

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

**Looking after your medicine**

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

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 any other place where there is high humidity), or
- in the car or on window sills (heat and dampness can destroy some medicines).

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

**When to discard your medicine**

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.

**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><b>Bleeding-related:</b></p> <ul style="list-style-type: none"> <li>bleeding or bruising more easily</li> </ul> <p><b>Swelling related:</b></p> <ul style="list-style-type: none"> <li>swelling of the arms, feet or legs</li> </ul> <p><b>Injection site related:</b></p> <ul style="list-style-type: none"> <li>stinging or swelling around the injection area</li> </ul> <p><b>Infection:</b></p> <ul style="list-style-type: none"> <li>chest or throat infection, difficulty breathing, cough</li> </ul> <p><b>Urinary:</b></p> <ul style="list-style-type: none"> <li>pain with urination or increased urgency and/or frequency of urination.</li> </ul> <p><b>Flu-like symptoms:</b></p> <ul style="list-style-type: none"> <li>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.</li> </ul> <p><b>General:</b></p> <ul style="list-style-type: none"> <li>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</li> <li>headache</li> <li>weakness</li> <li>nausea and vomiting</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<p><b>Headache related:</b></p> <ul style="list-style-type: none"> <li>stabbing, migraine-like headache</li> </ul> <p><b>Heart symptoms:</b></p> <ul style="list-style-type: none"> <li>cardiac (heart) symptoms such as chest pain, shortness of breath, double vision, dizziness, feeling lightheaded or tingling of extremities (fingers and toes).</li> </ul> <p><b>Swelling related:</b></p> <ul style="list-style-type: none"> <li>swelling, pain, tenderness, warmth or discolouration of one leg or arm or along a vein in your leg or arm</li> </ul> <p><b>Breathing related:</b></p> <ul style="list-style-type: none"> <li>sudden shortness of breath, chest pain, palpitations or coughing up blood</li> <li>sudden onset of wheezing or difficulty breathing, swollen tongue, face or throat</li> </ul> <p><b>Coordination:</b></p> <ul style="list-style-type: none"> <li>sudden trouble walking, speaking, seeing or understanding what someone is saying</li> </ul> <p><b>Skin related:</b></p> <ul style="list-style-type: none"> <li>severe skin reactions, hives, blisters or rash that may cover your whole body</li> </ul> <p><b>Allergic reaction related:</b></p> <ul style="list-style-type: none"> <li>A severe allergic reaction (very rare) can occur, especially just after an injection. This must be treated at once. Symptoms of an allergic reaction include swelling, itching, rash or breathing difficulties.</li> </ul>	<p><b>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.

#### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects in Australia to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems) or in New Zealand to the Centre of Adverse Reactions Monitoring (CARM) online

at <https://nzphvc.otago.ac.nz/consumer-reporting/>. 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 taking any of your medicines.**

## 7. Product details

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

### What NeoRecormon contains

<b>Active ingredient (main ingredient)</b>	epoetin beta (recombinant human erythropoietin)
<b>Other ingredients (inactive ingredients)</b>	urea sodium chloride monobasic sodium phosphate dibasic sodium phosphate dodecahydrate calcium chloride dihydrate polysorbate 20 glycine leucine isoleucine threonine glutamic acid phenylalanine
<b>Potential allergens</b>	NeoRecormon contains phenylalanine as an inactive ingredient and you should consult your doctor about the risks.

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

### What NeoRecormon looks 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.

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).

# Not available in New Zealand

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

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

### Who distributes NeoRecormon

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.

This leaflet was prepared in July 2023.