

# NEORECORMON<sup>®</sup>

Contains the active ingredient epoetin beta (rch) [recombinant human erythropoietin]

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about NEORECORMON<sup>®</sup>.

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 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 called hormones.

NEORECORMON is similar to one of the hormones made naturally by the kidneys (and a small proportion by the liver) which stimulates the production of red blood cells in the bone marrow and spleen.

NEORECORMON works by increasing red blood cell production

and is used in the treatment of various types of anaemia. Anaemia is a condition where the body does not produce enough red blood cells.

Anaemia may occur if a person has kidney damage or failure. There are also other circumstances where a person has normally functioning kidneys but may still have anaemia (such as patients receiving chemotherapy). NEORECORMON may be useful in these other circumstances.

NEORECORMON is also used when a patient's own blood is donated and stored for transfusion prior to major surgery. This means that the patient should not need to accept a transfusion from a blood bank.

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 controlled
- you or your baby has phenylketonuria (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 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 applies 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, an unexpected effect.

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

#### Use in children

NEORECORMON is safe to be used in children, including premature infants.

## **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 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
- you have any other health problems including:
  - blood clotting diseases
  - high blood pressure - it is important to follow your doctor's instructions to control your blood pressure, including any dietary restrictions
  - cancer
  - epilepsy
  - kidney disease
  - liver disease
  - any other illness or health problems. A number of conditions such as vitamin deficiencies may affect how well you respond to NEORECORMON.
- you are allergic to any other medicines, foods, dyes or preservatives.

## **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 has more information on medicines to be careful with or avoid while taking NEORECORMON.

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## **How to use NEORECORMON**

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

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

### **How much to inject**

Your doctor will tell you how much NEORECORMON to inject according to your individual needs.

If necessary, your dose may be changed by your doctor during therapy according to your response.

Your doctor will keep track of your response to NEORECORMON by asking questions and performing occasional laboratory tests.

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

### **How to inject it**

NEORECORMON is administered by subcutaneous (under the skin) or intravenous (into the vein) injection.

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.

If your doctor has decided to give you NEORECORMON by intravenous injection, you will be given the injections by a nurse during your dialysis session.

A patient support kit is available to assist patients who self-inject their NEORECORMON. Please enrol using the form at the end of this leaflet or for more information contact your doctor, healthcare professional or Roche Medical Information service (1800 233 950).

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

### **Directions for subcutaneous injection**

The following directions are for subcutaneous injection only.

You should read these directions from beginning to end before starting so that each step of the procedure becomes familiar. These instructions must be carefully followed. Consult your doctor if you require further instructions.

Remember that cleanliness is vital.

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

Before you begin

1. Wash your hands thoroughly.
2. Find a clean, comfortable area.
3. Gather all the medicinal supplies you will need:
  - An alcohol swab.
  - Some cotton wool.
  - A sharps disposal bin.
4. 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 the medication.
5. Check the expiry date (EXP). Do not use NEORECORMON after the expiry date shown on the pre-filled syringe label.
6. Check that the liquid has no discolouration, cloudiness or particles. The liquid should look clear and colourless.

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

7. Remove the protective covering from the needle package.
8. Remove the rubber cap from the end of the syringe.
9. Place the needle firmly on the end of the syringe.
10. Remove the protective cap from the end of 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 each time 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.

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. Place the syringe and needle (as one) 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.

**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.

### ***If you forget to use NEORECORMON***

**If it is almost time for your injection, skip the injection you missed and use your next injection when you are meant to. Otherwise, use it as soon as you remember, and then go back to using it as you would normally.**

**Do not use a double injection 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) for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have used too much NEORECORMON, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

**Keep telephone numbers for these places handy.**

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## **While you are using NEORECORMON**

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***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 consulting a pharmacist.**

If you have blood pressure problems it is important to follow your doctor's instructions to control your blood pressure, including any dietary restrictions, 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 need to give you regular blood tests.

### ***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.**

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## **Side effects**

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**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:**

- headache
- increase in blood pressure or worsening of existing high blood pressure. Symptoms could include sudden, stabbing migraine-like headaches. Your doctor will regularly check your blood pressure, particularly at the beginning of therapy.
- bleeding or bruising more easily
- swelling of the arms, feet or legs
- stinging 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
- cardiac (heart) symptoms such as chest pain, shortness of breath, double vision, dizziness, or tingling of extremities

A severe allergic reaction (very rare) can occur, especially just after an injection. This must be treated at once. If you notice unusual wheezing or difficulty breathing; swollen tongue, face or throat, or swelling around the injection site; if you feel lightheaded or faint; or if you collapse, contact your doctor or go to Accident and Emergency at your nearest hospital.

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. Others may occur in some people and there may be some side effects 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.**

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## **After using NEORECORMON**

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### ***Storage***

**Always keep this medicine in the carton, in the fridge, until it is time to use it.**

If you take the pre-filled syringes out of the pack they may not keep well.

**Store NEORECORMON pre-filled syringes in the fridge at 2 to 8 degrees Celsius. Do not freeze.**

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 degrees Celsius).

**Protect NEORECORMON pre-filled syringes from light.**

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

Heat and dampness can destroy some medicines.

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

In an appropriate container on the top shelf of a fridge is a good place to store NEORECORMON.

**NEORECORMON pre-filled syringes are for single use in one person only.**

The pre-filled syringes should be used once only and any remaining contents should be discarded with the needle in an appropriate container.

### **Disposal**

**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**

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### **Availability**

NEORECORMON pre-filled syringes are available in the following strengths:

- 1,000 IU/0.3 mL solution (6 per pack),
- 2,000 IU/0.3 mL solution (6 per pack),
- 3,000 IU/0.3 mL solution (6 per pack),
- 4,000 IU/0.3 mL solution (6 per pack),
- 5,000 IU/0.3 mL solution (6 per pack),

- 6,000 IU/0.3 mL solution (6 per pack),
- 10,000 IU/0.6 mL solution (6 per pack),
- 20,000 IU/0.6 mL solution (6 per pack),
- 30,000 IU/0.6 mL solution (1 per pack).

### **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 (rch) (recombinant human erythropoietin)

#### **Inactive ingredients**

Each pre-filled syringe also contains:

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

4,000 IU/0.3 mL AUST R 104264  
5,000 IU/0.3 mL AUST R 104265  
6,000 IU/0.3 mL AUST R 104266  
10,000 IU/0.6 mL AUST R 104267  
20,000 IU/0.6 mL AUST R 104268  
30,000 IU/0.6 mL AUST R 104269

This leaflet was prepared on 17 July 2007.

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## **Sponsor**

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Roche Products Pty Limited  
ABN 70 000 132 865  
4 - 10 Inman Road  
Dee Why NSW 2099

Customer enquiries: 1 800 233 950

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

Australian Registration Numbers:  
1,000 IU/0.3 mL AUST R 104258  
2,000 IU/0.3 mL AUST R 104262  
3,000 IU/0.3 mL AUST R 104263

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## More Information

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# P.I.N.K Enrolment Form

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The Patient Information NeoRecormon Kit ( P.I.N.K ) . program is a service provided for patients who have been prescribed NeoRecormon. It includes an educational website and practical items such as a sharp's container, swabs and cooler bags to assist with self administration.

To enrol in the program simply fill in this enrolment form and mail to:

P.I.N.K. Program  
PO Box 1207  
Brookvale NSW 2100

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### Patient Details

Title
First Name
Surname
Postal Address
Postcode

Date commenced NeoRecormon:

Prescribing Physicians Name:

Roche is collecting your personal information on this enrolment form so that you can participate in the P.I.N.K. Program. Your personal information may be passed on to our agencies for the sole purpose of administering this service. Your personal information will not be disclosed to anyone else. If you would like to review or modify any part of the information that you have submitted, please write to P.I.N.K. program, PO Box 1207, Brookvale, NSW 2100.