SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Recormon® 2 000 IU/0,3 mℓ Injection

Recormon® 4 000 IU/0,3 mℓ Injection

Recormon® 6 000 IU/0,3 mℓ Injection

Recormon® 10 000 IU/0,6 mℓ Injection

Read all of the leaflet carefully before you start taking/using Recormon

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- Recormon has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT RECORMON CONTAINS

- Recormon 2 000 IU/0,3 mℓ pre-filled syringe

  Each pre-filled syringe contains 2 000 IU equivalent to 16,7 µg epoetin beta (recombinant human erythropoietin - a hormone which stimulates the production of red blood cells) in 0,3 mℓ solution for injection.
- Recormon 4 000 IU/0,3 mℓ pre-filled syringe

  Each pre-filled syringe contains 4 000 IU equivalent to 33,4 µg epoetin beta (recombinant human erythropoietin - a hormone which stimulates the production of red blood cells) in 0,3 mℓ solution for injection.
- Recormon 6 000 IU/0,3 mℓ pre-filled syringe

  Each pre-filled syringe contains 6 000 IU equivalent to 50,0 µg epoetin beta (recombinant human erythropoietin - a hormone which stimulates the production of red blood cells) in 0,3 mℓ solution for injection.

- Recormon 10 000 IU/0,6 mℓ pre-filled syringe

  Each syringe contains 10 000 IU equivalent to 83 µg epoetin beta (recombinant human erythropoietin - a hormone which stimulates the production of red blood cells) in 0,6 mℓ solution for injection.

  The other ingredients are urea, sodium chloride, polysorbate 20, sodium dihydrogen phosphate dihydrate, disodium hydrogen phospate dodecahydrate, calcium chloride dihydrate, glycine, leucine, isoleucine, threonine, glutamic acid, phenylalanine and water for injection.

WHAT RECORMON IS USED FOR

Recormon contains a hormone called *epoetin beta*, which stimulates the production of red blood cells. Epoetin beta is produced by a specialised genetic technology and works in exactly the same way as the natural hormone erythropoietin.

Recormon injections are used for:

- **Treating symptomatic anaemia caused by chronic kidney disease** (renal anaemia) in patients on dialysis, or not yet on dialysis.
- **Preventing anaemia in premature infants** (weighing 750 to 1 500 g and born at less than 34 weeks).
- **Treating anaemia with related symptoms in adult cancer patients receiving chemotherapy**
- **Treating people donating their own blood before surgery.** The injections of epoetin beta will increase the amount of blood that can be taken from your body before surgery and given back during or after the operation (this is an *autologous transfusion).*

BEFORE RECEIVING RECORMON

You should not receive Recormon:

- **if you are allergic *(hypersensitive)*** to epoetin beta or any of the other ingredients of Recormon

- **if you have blood pressure problems** that cannot be controlled
- **if you are donating your own blood before surgery, and:**
  - you had a **heart attack** or **stroke** in the month before your treatment
  - you have **unstable angina** pectoris – new or increasing chest pain
  - you are **at risk of blood clots** in the veins *(deep venous thrombosis)* – for example, if you have had clots before.

If any of these apply to you, or might apply, **tell your doctor at once.**

Take special care with Recormon:

- **if your anaemia does not improve with Recormon**
- **if you are low in certain B vitamins** *(folic acid or vitamin B12)*
- **if you have very high levels of aluminium** in your blood
- **if your blood platelet count is high**
- **if you have chronic liver disease**
- **if you have epilepsy**
- **if you have developed anti-erythropoietin antibodies and *pure red cell aplasia*** (reduced or stopped production of red blood cells) during prior exposure to any erythropoietic substance. In this case you should not be switched to Recormon.

If any of these apply to you, **tell your doctor.**

If you are a cancer patient you should be aware that Recormon may act as a blood cell growth factor and in some circumstances may have a negative impact on your cancer. Depending on your individual situation a blood transfusion may be preferable. Please discuss this with your doctor.

If you are a patient with chronic kidney disease, your doctor will check that your haemoglobin does not exceed a certain level as high haemoglobin could put you at risk of having a problem of the heart or the blood vessels and could increase risk of death.

If you are a nephrosclerotic patient and you are not on dialysis, your doctor will decide whether treatment is right for you. This is because one cannot rule out a possible acceleration of progression of kidney disease with absolute certainty.

Your doctor may do regular blood tests to check:

- **your potassium level.** If you have high or rising potassium levels your doctor may reconsider your treatment
- **your blood platelet count.** The number of platelets can rise slightly to moderately during Recormon treatment, and this can cause changes in blood clotting.

If you are a kidney patient under haemodialysis, your doctor may adjust your dose of heparin. This should avoid a blockage in the tubing of the dialysis system.

If you are kidney patient under haemodialysis and at risk of shunt thrombosis, blood clots *(thromboses)* may form in your *shunt* (vessel used for connection to the dialysis system). Your doctor will manage it.

If you are donating your own blood before surgery, your doctor will need to:

- check that you are capable of giving blood, especially if you weigh less than 50 kg
- check that you have a sufficient level of red blood cells *(haemoglobin of at least 11 g/dℓ)*
- make sure that the correct amount of your blood is donated.

Do not misuse Recormon

Misuse of Recormon by healthy people may lead to an increase in blood cells and consequently thicken the blood. This can in turn lead to life-threatening complications of the heart or blood vessels.

Pregnancy and breastfeeding

There is not much experience with Recormon in pregnant women or women who are breastfeeding. Ask your doctor or pharmacist for advice before receiving Recormon.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before receiving Recormon.

Driving and using machinery

No effects on ability to drive or use machines have been observed.

Important information about some of the ingredients of Recormon

Recormon contains phenylalanine. Recormon may be harmful for people with phenylketonuria.

If you have *phenylketonuria*, **talk to your doctor** about your treatment with Recormon.

Recormon is almost sodium-free.

Taking other medicines with Recormon

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

HOW TO USE RECORMON

Recormon therapy is started by a doctor who is an expert on your condition. The first dose is usually given to you under medical supervision, because of the possibility of an allergic reaction. Recormon injections can then be given by a trained nurse, doctor or other professional. Once you have been shown how, you can also inject the solution yourself.

The Recormon pre-filled syringe is ready for use. Each syringe should be used for a single injection only. Do not mix Recormon with other injections or infusion solutions.

Instructions for use

First wash your hands!

1 **Remove one syringe** from the pack.

Check the liquid in the syringe:

- is it **clear?**
- is it **colourless?**
- is it **free of particles?**

If the answer is NO to any question, do not administer the injection.

Dispose of it and start again with a different syringe.

If you answer **YES** to all three, remove the cap from the syringe and go to step 2.

2 **Remove a needle** from the pack, fix it securely on to the syringe and remove the protective cap from the needle.

3 **Expel air from the syringe** and needle. Do this by lightly tapping on the upper half of the syringe. This will cause any air bubbles to rise to the top. Then hold the syringe vertically and the needle upwards, and gently push the plunger upwards. Keep pushing the plunger until the amount of Recormon in the syringe is as prescribed.

4 **Clean the skin at the injection site** using an alcohol wipe. Form a skin fold by pinching the skin between thumb and forefinger.

5 **Holding the syringe near the needle, insert the needle** into the skin fold with a quick, firm action. Inject the Recormon solution. Withdraw the needle quickly and apply pressure over the injection site with a dry, sterile pad.

Recormon dosing

The dose of Recormon depends on your disease condition, the way the injection is given (under the skin or into a vein) and your body weight. Your doctor will work out the right dose for you.

If you inject too much Recormon

Do not increase the dose your doctor has given you. If you think you have injected more Recormon than you should, contact your doctor.

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take Recormon

If you have missed an injection, or injected too little, talk to your doctor. Do not administer a double dose.

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of Recormon, ask your doctor or pharmacist.

Do not share medicines prescribed for you with another person.

POSSIBLE SIDE EFFECTS

Recormon can cause side effects.

Not all side effects reported for Recormon are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving Recormon, please consult your doctor, pharmacist or other healthcare professional for advice.

Side effects which can affect any patient:

- Lower levels of iron in the blood. Almost all patients have to be treated with iron supplements during their Recormon therapy.

Less frequent:

- Allergies or skin reactions, such as rash or hives, itching or reactions around the injection site have occurred.
- A severe form of allergic reaction has occurred, especially just after an injection. It needs to be treated immediately. If you get 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, call your doctor immediately.
- Flu-like symptoms. These include fever, chills, headaches, pain in the limbs, bone pain and/or feeling generally unwell. People experienced this especially when they just started treatment. These reactions were usually mild to moderate and went away within a few hours or days.

Additional side effects in people with chronic kidney disease (renal anaemia)

Frequent:

- Increase in blood pressure, worsening of existing high blood pressure and headache. Your doctor will regularly check your blood pressure, particularly at the beginning of therapy. Your doctor may treat the high blood pressure with medicines or temporarily interrupt your Recormon therapy.
- Headaches, especially sudden, stabbing, migraine-like headaches, confusion, speech disturbance, unsteady walking, fits or convulsions**.** These may be signs of severely elevated blood pressure *(hypertensive crisis)*, even if your blood pressure is usually normal or low. Call a doctor; it needs to be treated at once.
- If you have low blood pressure or shunt complications you may be at risk of *shunt thrombosis* (a blood clot in the vessel used for connection to the dialysis system).

Less frequent:

- Rising levels of potassium or phosphates in the blood. This can be treated by your doctor.
- Pure red cell aplasia (PRCA) caused by neutralising antibodies has been observed during erythropoietin therapy, including in isolated cases during therapy with Recormon. PRCA means that the body stopped or reduced the production of red blood cells. This causes severe anaemia, symptoms of which would include unusual tiredness and a lack of energy. If your body produces neutralising antibodies, your doctor will discontinue therapy with Recormon, and determine the best course of action to treat your anaemia.

Additional side effects in adults receiving chemotherapy for cancer

- Increase in blood pressure and headache may occasionally occur. Your doctor may treat the high blood pressure with medicines for high blood pressure.
- An increase in the occurrence of blood clots has been observed.

Additional side effects in people donating their own blood before surgery

- A slight increase in the occurrence of blood clots has been observed.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

STORING AND DISPOSING OF RECORMON

Store all medicines out of reach of children.

- Do not use Recormon after the expiry date which is stated on the pack.
- Keep the pre-filled syringe in the outer carton, in order to protect from light.
- Store in a refrigerator (2 °C - 8 °C).
- The syringe can be removed from the refrigerator and left at room temperature for a single period of maximum 3 days (but not above 25 °C).

Disposal: The following points should be strictly adhered to regarding the use and disposal of syringes and other medicinal sharps:

- Needles and syringes should never be reused.
- Place all used needles and syringes into a sharps container (puncture-proof disposable container).
- Keep this container out of the reach of children.
- Placing used sharps containers in the household waste should be avoided.

Dispose of the full container according to local requirements or as instructed by your healthcare provider.

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.

PRESENTATION

Pack size of 1 or 6 pre-filled syringes.

Not all pack sizes may be marketed.

IDENTIFICATION

Colourless, clear to slightly opalescent solution. Recormon is provided as a solution for injection in 1 or 6 pre-filled syringes with 1 or 6 needles.

REGISTRATION NUMBERS

Recormon 2 000 IU/0,3 mℓ: 37/8.3/0567

Recormon 4 000 IU/0,3 mℓ: 37/8.3/0568

Recormon 6 000 IU/0,3 mℓ: 37/8.3/0569

Recormon 10 000 IU/0,6 mℓ: 38/8.3/0500

NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER

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Roche Ethical Assistance Line (REAL) toll-free: 0800 21 21 25

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Last Revision:

Recormon 2000 IU/0,3 mL; 4000 IU/0,3 mL; 6000 IU/0,3 mL: 16 August 2022

Recormon 10 000 IU/0,6 mL: 12 August 2022