

RECORMON®

Epoetin beta (2000 iu/0.3 mL, 4000 iu/0.3 mL, 5000 iu/0.3 mL)

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What Recormon is used for

Recormon is used to treat anaemia. Anaemia is a condition where your blood does not have enough red blood cells and your haemoglobin (a protein which transports oxygen in the blood) level is too low. Therefore, your body's tissues might not receive enough oxygen.

Anaemia may occur if a person has kidney disease. There are also other circumstances where a person has normal functioning kidneys but still has anaemia (such as patients receiving chemotherapy). Recormon may also be useful in these circumstances.

Recormon is also used when a patient's own blood is donated and stored for transfusion prior to major surgery. This means that the patient will not need to receive a transfusion from a blood bank. Recormon is also used to treat anaemia in premature babies.

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

How Recormon works

Recormon 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).

Erythropoietin is a natural hormone produced by the kidneys which stimulates the production of red blood cells in the bone marrow and spleen. Like erythropoietin, Recormon works by increasing the number of red blood cells and haemoglobin level in your blood.

Before you use Recormon

- When you must not use it

Do not take Recormon 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). Recormon 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
 - you have new or increasing chest pain
 - 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 Recormon, talk to your doctor.

Use in children

Recormon is safe to be used in children over 2 years old who have anaemia as a result of kidney disease.

Recormon is also safe for treating anaemia in premature babies.

- Before you start to use it

Your doctor will check the amount of iron in your blood before and during your Recormon treatment. If the amount is too low, your doctor may recommend you to take iron supplements.

Tell your doctor if:

- you are pregnant or plan to become pregnant. Recormon is not generally recommended for use in pregnant women.
- you are breastfeeding or plan to breastfeed.

It has not been possible to determine whether Recormon passes into the breast milk following injection.

Your doctor will discuss the risks and benefits of using Recormon if you are pregnant or breastfeeding.

- 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 taking blood pressure medicines or making 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 illnesses or health problems
- you are using Recormon for donating your own blood before surgery and you weigh less than 50 kg.
- you are allergic to any other medicines, foods, dyes or preservatives.

Healthy people should not receive Recormon as it 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 without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interact with Recormon 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 Recormon.

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

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How to use Recormon

Recormon can be given by your doctor or nurse. Alternatively your doctor, nurse or pharmacist may teach you or your carer how to inject Recormon. Do not inject yourself with Recormon 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.

- How much to use

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

Depending on your response to treatment, your dose may be changed by your doctor if necessary.

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

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

How to inject Recormon

Recormon can be administered via subcutaneous (under the skin) or intravenous (into the vein) injection. Your doctor will decide which method is suitable for you.

Intravenous administration

Only a health professional should administer Recormon intravenously.

Subcutaneous administration

It is recommended that the first dose of Recormon is to 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.

If your doctor has directed you to use Recormon by subcutaneous injection, please follow the instructions below. These instructions must be carefully followed. 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

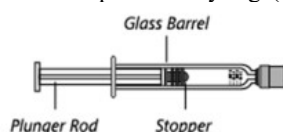
- **Do not** take the needle cap off until you are ready to inject Recormon.

- **Do not** try to take the syringe apart at any time.
- **Do not** reuse the same syringe.
- **Do not** use if the syringe has been dropped or damaged.
- **Do not** leave the syringe unattended.
- Keep the syringe and needle and the puncture-resistant or sharps disposal container out of reach of children.
- Contact your healthcare professional if you have any questions.

Supplies needed to give your injection

Included in the box:

- Recormon pre-filled syringe(s).



- Injection needle(s) 27G ½ used for priming, setting the dose and injecting the medicine.

Note: Each Recormon carton contains 6 syringes/6 needles.

- Package leaflet with Instructions for Use.

Not included in the box:

- 1 alcohol swab.
- 1 dry sterile pad.
- 1 puncture-resistant container or sharps container for safe disposal of rubber cap, needle cap and used syringe.

Preparing for injection

- 1 Find a well-lighted, clean, flat, working surface.
 - Take the carton with the syringe(s) and needle(s) out of the refrigerator.
- 2 Check that the carton has not been damaged and check the expiration date on the carton has not passed.
 - **Do not** use if the expiration date has passed, if the syringe is dropped or damaged, or if the carton appears to be tampered with. In this case, proceed to step 17 and contact your healthcare provider.
- 3 Take one syringe out of the carton and one needle. Be careful when taking out the syringe. Make sure you always hold the syringe on the glass barrel.
 - **Do not** flip the carton upside down to remove the syringe.

- **Do not** handle the syringe by holding the plunger or needle cap. *Remark: If you have a multipack, put the carton with the remaining syringe(s) and needle(s) back into the refrigerator.*

- 4 Inspect the syringe and needle closely

- Check the syringe and needle for any damage. **Do not** use the syringe if you have dropped the syringe or if any part of the syringe appears to be damaged.

- Check the expiration date on the syringe and the needle. **Do not** use the syringe or the needle if the expiration date has passed.

- Check the liquid in the syringe. The liquid should be clear and colorless. **Do not** use the syringe if the liquid is cloudy, discolored, or has particles.

- 5 Place the syringe on a clean, flat surface.

- Set aside the syringe for 30 minutes so it can warm up on its own to room temperature. Leave the needle cap on while it warms up.

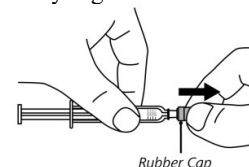
- **Do not** speed up the warming process in any way, and **do not** put the syringe in a microwave or in warm water.

Remark: If the syringe does not reach room temperature, this could cause the injection to feel uncomfortable and make it hard to push the plunger.



- 6 Attach the needle to the syringe.

- Remove the needle from its blister.
- Remove the outer packaging from the needle. **Do not** remove the needle cap.
- Pull the rubber cap off the end of the syringe.



- Dispose of the rubber cap in a puncture-resistant or sharps container immediately.
- **Do not** touch the tip of the syringe.

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- **Do not** push or pull the plunger.
 - Hold the syringe by the barrel and push the needle onto the syringe.
 - Gently twist until it is fully attached.
- 7 Place the syringe on a clean, flat surface until ready to use.
 - 8 Wash your hands with soap and water.
 - 9 Choose an injection site:
 - The recommended injection sites are the top of your thigh or the lower part of your abdomen below the belly button.



- **Do not** inject within 5 cm (2 inches) area directly around your belly button.
 - Choose a different injection site for each new injection.
 - **Do not** inject into moles, scars, bruises or areas where the skin is tender, red, hard or not intact.
 - **Do not** inject into vein or into a muscle.
- 10 Wipe the injection site with an alcohol swab and let it air dry for 10 seconds.

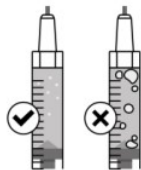


- **Do not** fan or blow on the cleaned area.
- **Do not** touch the injection site again before giving the injection.

Administering the subcutaneous injection

- 11 Hold the syringe and needle tightly at the hub and carefully pull the injection needle cap away from the syringe. Use the syringe within 5 minutes of removing the cap; otherwise, the needle may clog.
 - **Do not** hold the plunger while you remove the needle cap.
 - **Do not** touch the needle after removing the needle cap.
 - **Do not** re-cap the needle.
 - **Do not** straighten needle if needle is bent or damaged.
 Throw away the needle cap in a sharps container immediately.
- 12 Hold the syringe with the needle pointing up. Remove the larger air

bubbles by gently tapping the syringe barrel with your fingers until the air bubbles rise to the top of the syringe. Then, slowly push the plunger up to push the air bubbles out of the syringe.



- 13 Adjust to your prescribed dose by slowly pushing the plunger.
- 14 Pinch the selected injection site and fully insert the needle at a 45° to 90° angle with a quick, firm action.
 - **Do not** touch the plunger while inserting the needle into the skin.
 - **Do not** insert the needle through clothing.
 Once the needle is inserted, release the pinch and hold the syringe tightly in place.
- 15 Slowly inject your prescribed dose by gently pushing the plunger all the way down.
 - Remove the needle and syringe from the injection site at the same angle as inserted.

After the injection

- 16 There may be a little bleeding at the injection site. You can press dry sterile pad over the injection site. **Do not** rub the injection site.
 - If needed, you may cover the injection site with a small bandage.
 - In case of skin contact with medicine, wash the area that touched the medicine with water.
- 17 Put your used syringe in a sharps disposal container right away after use.
 - **Do not** try to remove the used injection needle from the used syringe.
 - **Do not** recap the injection needle with the cap.
 - **Do not** throw away (dispose of) the syringe in your household trash.

Important: Always keep the sharps disposal container out of reach of children.

- When to use it

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

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

- How long to use it

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

Continue using Recormon until your doctor tells you to stop, even if you feel well.

- If you forget to use it

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 Recormon as you normally would.

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

Because Recormon 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 (overdose)

Immediately contact your doctor or go to your nearest Accident and Emergency department if you think that you or anyone else may have used too much Recormon.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Use Recormon exactly as your doctor has prescribed.

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

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 all your doctor's instructions to control your blood pressure, including taking blood pressure medicines and making changes to your diet.

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

Tell your doctor if you become pregnant while using Recormon.

Tell your doctor if, for any reason, you have not used Recormon 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 Recormon by asking questions and performing tests such as taking your blood pressure or taking blood.

- Things you must not do

Do not stop using Recormon 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 Recormon to anyone else even if they have the same condition as you.

Do not use Recormon 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 while driving or operating machinery until you know how Recormon affects you.

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

Side effects

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

Recormon 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 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.
- rash, itch, skin reactions

Tell your doctor **immediately** if you notice the following:

- worsening high blood pressure symptoms such as stabbing, migraine-like headache, speech disturbance or impaired gait
- cardiac (heart) symptoms such as chest pain, shortness of breath, double vision, dizziness, or tingling of extremities (fingers and toes).
- Shunt Thromboses

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 the Accident and Emergency department.

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 do not understand anything in this list.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Recormon

- Storage

Store Recormon pre-filled syringes in the fridge at 2°C to 8°C. Do not freeze. Always keep Recormon in its carton, in the fridge, until it is time to use it. This will protect Recormon from being affected by light.

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

You can use Recormon if it has been left out of the fridge for not longer than 3 days (at one occasion only) at room temperature (up to 25°C).

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

Do not leave Recormon in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Recormon where young children cannot reach it.

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

- 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.

Medicines should not be disposed of via wastewater and disposal through household waste should be avoided.

If your doctor tells you to stop using Recormon, 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

- What it looks like

Recormon pre-filled syringes are available in the following strengths (syringe plungers and packaging are coloured as indicated below to enable easy identification of strength):

- 2000 IU/0.3 mL (orange)
- 4000 IU/0.3 mL (red)
- 5000 IU/0.3 mL (grey)

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

Recormon 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

- urea
- sodium chloride
- sodium monohydrogen phosphate
- sodium dihydrogen phosphate
- calcium chloride
- polysorbate 20
- glycine
- leucine
- isoleucine
- threonine
- glutamic acid
- phenylalanine

- MAL number :

- Recormon PFS 2000 IU/0.3 ml
MAL20020495ARZ
MAL20081783ARSZ
- Recormon PFS 4000 IU/0.3 ml
MAL20020496ARZ
MAL15045175ACRSZ
- Recormon PFS 5000 IU/0.3 ml
MAL20020497ARZ
MAL20081784ARSZ

Manufacturer

Made for

F. Hoffmann-La Roche Ltd, Basel, Switzerland

by Vetter Pharma Fertigung GmbH & Co. KG, Ravensburg, Germany.

Made for

F. Hoffmann-La Roche Ltd, Basel, Switzerland
by Roche Diagnostics GmbH, Mannheim, Germany

Product Registration Holder

Roche (M) Sdn. Bhd.
Level 21, The Pinnacle,
Persiaran Lagoon, Bandar Sunway,
47500 Subang Jaya,
Selangor, Malaysia.

Date of Revision

December 2022

Serial Number

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