Package leaflet: Information for the user

Retacrit 1 000 IU/0.3 mL solution for injection in pre-filled syringe
Retacrit 2 000 IU/0.6 mL solution for injection in pre-filled syringe
Retacrit 3 000 IU/0.9 mL solution for injection in pre-filled syringe
Retacrit 4 000 IU/0.4 mL solution for injection in pre-filled syringe
Retacrit 5 000 IU/0.5 mL solution for injection in pre-filled syringe
Retacrit 6 000 IU/0.6 mL solution for injection in pre-filled syringe
Retacrit 8 000 IU/0.8 mL solution for injection in pre-filled syringe
Retacrit 10 000 IU/1 mL solution for injection in pre-filled syringe
Retacrit 20 000 IU/0.5 mL solution for injection in pre-filled syringe
Retacrit 30 000 IU/0.75 mL solution for injection in pre-filled syringe
Retacrit 40 000 IU/1 mL solution for injection in pre-filled syringe

epoetin zeta

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Retacrit is and what it is used for
2. What you need to know before you use Retacrit
3. How to use Retacrit
4. Possible side effects
5. How to store Retacrit
6. Contents of the pack and other information

1. What Retacrit is and what it is used for

Retacrit contains the active substance epoetin zeta - a protein that stimulates the bone marrow to produce more red blood cells which carry haemoglobin (a substance that transports oxygen). Epoetin zeta is a copy of the human protein erythropoietin (ee-rith-roe-po-eh-tin) and acts in the same way.

- **Retacrit is used to treat symptomatic anaemia caused by kidney disease**

  - in children on haemodialysis.
  - in adults on haemodialysis or peritoneal dialysis.
  - in severely anaemic adults not yet undergoing dialysis.

  If you have kidney disease, you may be short of red blood cells if your kidney does not produce enough erythropoietin (necessary for red cell production). Retacrit is prescribed to stimulate your bone marrow to produce more red blood cells.

- **Retacrit is used to treat anaemia in adults receiving chemotherapy for solid tumours**, malignant lymphoma or multiple myeloma (bone marrow cancer) who may have a need for a blood transfusion. Retacrit can reduce the need for a blood transfusion in these patients.

- **Retacrit is used in moderately anaemic adults who donate some of their blood before** surgery, so that it can be given back to them during or after the operation. Because Retacrit stimulates the production of red blood cells, doctors can take more blood from these people.

- **Retacrit is used in moderately anaemic adults about to have major orthopaedic surgery** (*for example hip or knee replacement operations*), to reduce the potential need for blood transfusions.

- **Retacrit is used to treat anaemia in adults with a bone marrow disorder that causes a severe disruption in the creation of blood cells (myelodysplastic syndromes).** Retacrit can reduce the need for a blood transfusion.

2. What you need to know before you use Retacrit

Do not use Retacrit

- **If you are allergic** to epoetin zeta or any of the other ingredients of this medicine (listed in section 6).

- **If you have been diagnosed with Pure Red Cell Aplasia** (the bone marrow cannot produce enough red blood cells) after previous treatment with any product that stimulates red blood cell production (including Retacrit). See section 4.

- **If you have high blood pressure** not properly controlled with medicines.

- To stimulate the production of your red blood cells (so that doctors can take more blood from you) **if you cannot have transfusions with your own blood** during or after surgery.

- **If you are due to have major elective orthopaedic surgery** (such as hip or knee surgery), and you:
  - have severe heart disease
  - have severe disorders of the veins and arteries
  - have recently had a heart attack or stroke
  - can't take medicines to thin the blood

  Retacrit may not be suitable for you. Please discuss with your doctor. While on Retacrit, some people need medicines to reduce the risk of blood clots. **If you can't take medicines that prevent blood clotting, you must not have Retacrit**.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Retacrit.

Take special care with Retacrit

Retacrit and other products that stimulate red cell production may increase the risk of developing blood clots in all patients. This risk may be higher if you have other risk factors for developing blood clots *(for example, if you have had a blood clot in the past or are overweight, have diabetes, have heart disease or you are off your feet for a long time because of surgery or illness)*. Please tell your doctor about any of these things. Your doctor will help you to decide if Retacrit is suitable for you.

Talk to your doctor if any of the following apply to you. You may still be able to use Retacrit, but discuss it with your doctor first:

- **If you know you suffer**, or have suffered, from:

    - **high blood pressure;**
    - **epileptic seizures or fits**
    - **liver disease**
    - **anaemia from other causes**
    - **porphyria (a rare blood disorder)**

- **If you are a patient with chronic renal failure**, and particularly if you do not respond properly to Retacrit, your doctor will check your dose of Retacrit because repeatedly increasing your dose of Retacrit if you are not responding to treatment may increase the risk of having a problem of the heart or the blood vessels and could increase risk of myocardial infarction, stroke and death.

- **If you are a cancer patient** be aware that products that stimulate red blood cell production (like Retacrit) may act as a growth factor and therefore in theory may affect the progression of your cancer. **Depending on your individual situation a blood transfusion may be preferable. Please discuss this with your doctor.**

- **If you are a cancer patient**, be aware that use of Retacrit may be associated with shorter survival and a higher death rate in head and neck, and metastatic breast cancer patients who are receiving chemotherapy.

- **Serious skin reactions** including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported in association with epoetin treatment.

    SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Also, ulcers of mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications.

    If you develop a serious rash or another of these skin symptoms, stop taking Retacrit and contact your doctor or seek medical attention immediately.

Take special care with other products that stimulate red blood cell production:

Retacrit is one of a group of products that stimulate the production of red blood cells, like the human protein erythropoietin does. Your healthcare professional will always record the exact product you are using.

If you are given a product in this group other than Retacrit during your treatment, speak to your doctor or pharmacist before using it.

Other medicines and Retacrit

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you are taking a medicine called cyclosporin (used e.g. after kidney transplants), your doctor may order blood tests to check the level of cyclosporin while you are taking Retacrit.

Iron supplements and other blood stimulants may increase the effectiveness of Retacrit. Your doctor will decide if it is right for you to take them.

If you visit a hospital, clinic or family doctor, tell them you are having Retacrit treatment. It may affect other treatments or test results.

Pregnancy, breast-feeding and fertility

It is important to tell your doctor if any of the following apply to you. You may still be able to use Retacrit, but discuss it with your doctor first.

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- **If you are breast-feeding**.

No data on the effects of epoetin zeta on fertility are available.

Driving and using machines

Retacrit has no or negligible effect on the ability to drive and use machines.

Retacrit contains phenylalanine

This medicine contains 0.5 mg of phenylalanine in each mL.

Phenylalanine may be harmful if you have phenylketonuria, a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Retacrit contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

Retacrit contains polysorbate 20

This medicine contains a maximum of 0.1 mg of polysorbate 20 in each syringe, equivalent to a concentration of 0.1 mg/mL. Polysorbates may cause allergic reactions. Tell your doctor if you or your child have any known allergies.

3. How to use Retacrit

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Your doctor has carried out blood tests and decided you need Retacrit.

Retacrit may be given by injection:
- **Either** into a vein or a tube that goes into a vein (intravenously)
- **Or** under the skin (subcutaneously).

Your doctor will decide how Retacrit will be injected. Usually the injections will be given to you by a doctor, nurse or other health care professional. Some people, depending on why they need Retacrit treatment, may later learn how to inject themselves under the skin: see *Instructions on how to inject Retacrit yourself*.

Retacrit should not be used:
- after the expiry date on the label and outer carton
- if you know, or think that it may have been accidentally frozen, or

- if there has been a refrigerator failure.

The dose of Retacrit you receive is based on your bodyweight in kilograms. The cause of your anaemia is also a factor in your doctor deciding the correct dose.

Your doctor will monitor your blood pressure regularly while you are using Retacrit.

People with kidney disease

- Your doctor will maintain your haemoglobin level between 10 and 12 g/dL as a high haemoglobin level may increase the risk of blood clots and death. In children the haemoglobin level should be maintained between 9.5 and 11 g/dL.
- **The usual starting dose** of Retacrit for adults and children is 50 International Units (IU) per kilogram (/kg) of body weight given three times a week.
- For patients on peritoneal dialysis Retacrit may be given twice a week.
- For adults and children Retacrit is given as an injection either into a vein (intravenously) or a tube that goes into a vein. When this access (via a vein or tube) is not readily available, your doctor may decide that Retacrit should be injected under the skin (subcutaneously). This includes patients on dialysis and patients not yet on dialysis.
- Your doctor will order regular blood tests to see how your anaemia is responding and may adjust the dose, usually no more frequently than every four weeks. A rise in haemoglobin of greater than 2 g/dL over a four week period should be avoided.
- Once your anaemia has been corrected, your doctor will continue to check your blood regularly. Your Retacrit dose and frequency of administration may be further adjusted to maintain your response to treatment. Your doctor will use the lowest effective dose to control the symptoms of your anaemia.
- If you do not respond adequately to Retacrit, your doctor will check your dose and will inform you if you need to change doses of Retacrit.
- If you are on a more extended dosing interval (greater than once weekly) of Retacrit, you may not maintain adequate haemoglobin levels and you may require an increase in Retacrit dose or frequency of administration.
- You may be given iron supplements before and during Retacrit treatment to make it more effective.
- If you are having dialysis treatment when you begin treatment with Retacrit, your dialysis regime may need to be adjusted. Your doctor will decide this.

Adults on chemotherapy

- Your doctor may initiate treatment with Retacrit if your haemoglobin is 10 g/dL or less.
- Your doctor will maintain your haemoglobin level between 10 and 12 g/dL as a high haemoglobin level may increase the risk of blood clots and death.
- The starting dose is **either** 150 IU per kilogram bodyweight three times a week or 450 IU per kilogram bodyweight once a week.
- Retacrit is given by injection under the skin.
- Your doctor will order blood tests, and may adjust the dose, depending on how your anaemia responds to Retacrit treatment.
- You may be given iron supplements before and during Retacrit treatment to make it more effective.
- You will usually continue Retacrit treatment for one month after the end of chemotherapy.

Adults donating their own blood

- **The usual dose** is 600 IU per kilogram bodyweight twice a week.
- Retacrit is given by injection into a vein immediately after you have donated blood for 3 weeks before your surgery.

- You may be given iron supplements before and during Retacrit treatment to make it more effective.

Adults scheduled for major orthopaedic surgery

- **The recommended dose** is 600 IU per kilogram bodyweight once a week.
- Retacrit is given by injection under the skin each week for three weeks before surgery and on the day of surgery.
- If there is a medical need to reduce the time before your operation, you will be given a daily dose of 300 IU/kg for up to ten days before surgery, on the day of surgery and for four days immediately afterwards.
- If blood tests show your haemoglobin is too high before the operation, the treatment will be stopped.
- You may be given iron supplements before and during Retacrit treatment to make it more effective.

Adults with myelodysplastic syndrome

- Your doctor may initiate treatment with Retacrit if your haemoglobin is 10 g/dL or less. The aim of treatment is to maintain your haemoglobin level between 10 and 12 g/dL as a higher haemoglobin level may increase the risk of blood clots and death.
- Retacrit is given by injection under the skin.
- The starting dose is 450 IU per kilogram bodyweight once a week.
- Your doctor will order blood tests, and may adjust the dose, depending on how your anaemia responds to Retacrit treatment.

Instructions on how to inject Retacrit yourself

When treatment starts, Retacrit is usually injected by medical professional or a nurse. Later, your doctor may suggest that you or your caregiver learn how to inject Retacrit under the skin (*subcutaneously*) yourself.

- **Do not attempt to inject yourself unless you have been trained to do so by your doctor or nurse.**
- **Always use Retacrit exactly as instructed by your doctor or nurse.**
- **Only use Retacrit if it has been stored correctly – see section 5, *How to Store Retacrit*.**
- **Before use, leave the Retacrit syringe to stand until it reaches room temperature. This usually takes between 15 and 30 minutes.**

Only take one dose of Retacrit from each syringe.

If Retacrit is injected under the skin (subcutaneously), the amount injected is not normally more than one millilitre (1 mL) in a single injection. In case of larger volumes, more than one site should be chosen for the injection.

Retacrit is given alone and not mixed with other liquids for injection.

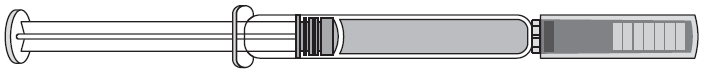
Do not shake Retacrit syringes. Prolonged vigorous shaking may damage the product. If the product has been shaken vigorously, don't use it.

How to inject yourself subcutaneously using a pre-filled syringe

- Remove the carton containing the pre-filled syringe from the refrigerator.
- Remove the blister tray containing the pre-filled syringe from the carton. When the carton contains blister trays with more than one pre-filled syringe, tear off the blister tray containing

one pre-filled syringe along the perforated part, and return the rest of the blister trays containing pre-filled syringes to the carton and return the carton to the refrigerator.

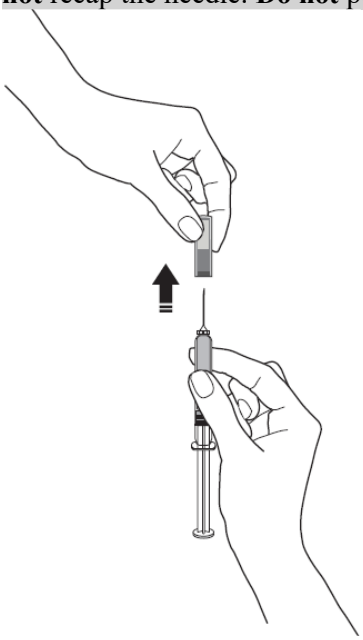
- Open the blister tray containing the pre-filled syringe after taking it out of the refrigerator. The liquid needs to come to room temperature. **Do not** remove the syringe's needle cover while allowing the pre-filled syringe to reach room temperature.



- Check the syringe, to make sure it is the right dose, has not passed its expiry date, is not damaged, and the liquid is clear and not frozen.
- **Do not use the pre-filled syringe if:**
    - The carton is open or damaged.
    - The medicine is cloudy or discoloured or the liquid has particles floating in it.
    - Any part of the pre-filled syringe appears cracked or broken or any of the liquid has leaked out of the syringe.
    - The pre-filled syringe has been dropped. The prefilled syringe may be broken even if you cannot see the break.
    - The needle cover is missing or not securely attached.
    - The expiration date printed on the label has passed.

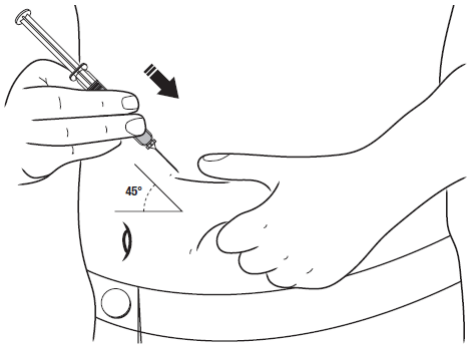
  In all cases above discard the pre-filled syringe and use a new pre-filled syringe.

- Choose an injection site. Good sites are the top of the thigh and around the tummy (abdomen) but away from the navel. Vary the site from day to day.
- Wash your hands. Use an antiseptic swab on the injection site, to disinfect it.
- Hold the pre-filled syringe by the body of the syringe with the covered needle pointing upward.
    - **Do not** hold by the plunger head, plunger or needle cover.
    - **Do not** pull back on the plunger at any time.
    - **Do not** remove the needle cover from the pre-filled syringe until you are ready to inject your medicine.
- Take the needle cover off the syringe by holding the barrel and pulling the needle cover straight off and away from your body carefully without twisting it. Throw away the needle cover. **Do not** recap the needle. **Do not** push the plunger, touch the needle or shake the syringe.



- Pinch a fold of skin between your thumb and index finger. **Do not** squeeze it.

- With your other hand, hold the pre-filled syringe like you would hold a pencil. Use a quick "dart-like" motion to insert the needle at an approximate 45 degree angle into the skin.

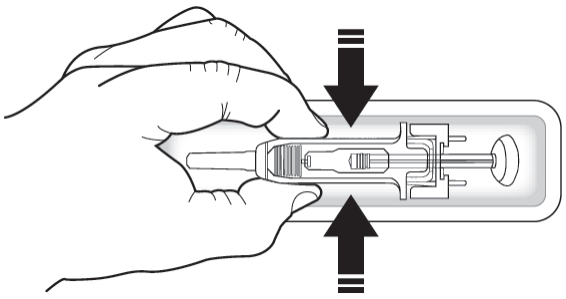


- Push the needle in fully. Your doctor or nurse may have shown you how to do this.
- Push the plunger with your thumb as far as it will go to inject the entire amount of liquid. Push it slowly and evenly, keeping the skin fold pinched.
- When the plunger is pushed as far as it will go, take out the needle and let go of the skin.
- When the needle is pulled out of your skin, there may be a little bleeding at the injection site. This is normal. You can press an antiseptic swab over the injection site for a few seconds after the injection.
- **Do not** try to replace the needle cover. Dispose of your used syringe in a sharps disposal (puncture-proof) container.
- **Never** put used syringes into your normal household waste bin.

How to inject yourself subcutaneously using a pre-filled syringe with a passive needle guard

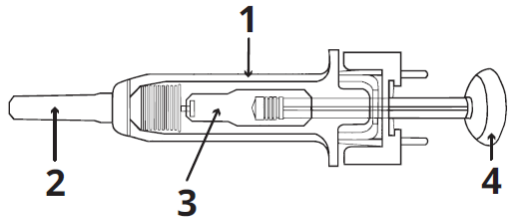
Your pre-filled syringe has a passive needle guard device attached to it in order to protect you from needle stick injury.

- Remove the carton containing the pre-filled syringe with passive needle guard from the refrigerator.
- Remove the blister tray containing the pre-filled syringe from the carton. When the carton contains blister trays with more than one pre-filled syringe, tear off the blister tray containing one pre-filled syringe along the perforated part, and return the rest of the blister trays containing pre-filled syringes to the carton and return the carton to the refrigerator.
- Open the blister tray containing the pre-filled syringe by peeling away the lid from the blister tray.
- Remove the pre-filled syringe from the blister tray by grasping from the syringe body.
    - **Do not** grasp the grey needle cover or the plunger rod.



- Check the syringe to make sure that the needle guard is covering the barrel of the pre-filled syringe. **Do not** push the needle guard over the needle cover before the injection. This may activate or lock the needle guard. If the needle guard is covering the needle that means it has been activated.

- The liquid needs to come to room temperature. **Do not** remove the syringe's needle cover while allowing the pre-filled syringe to reach room temperature.

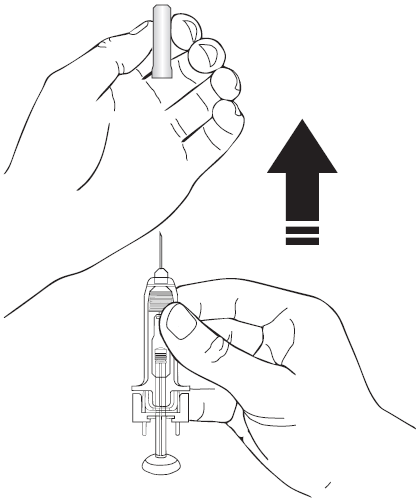


1 Needle Guard
2 Needle Cover
3 Medicine
4 Plunger Rod

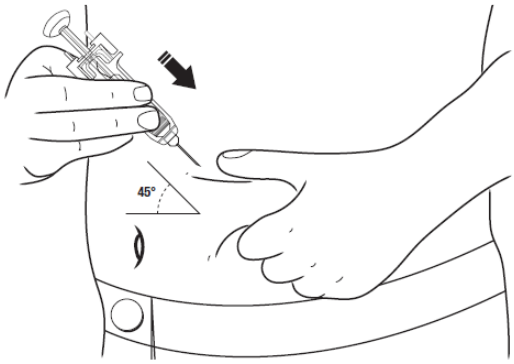
- Check the syringe, to make sure it is the right dose, has not passed its expiry date, is not damaged, and the liquid is clear and not frozen.
- **Do not use the pre-filled syringe if:**
    - The carton is open or damaged.
    - The needle guard is missing, detached or has been activated.
    - The medicine is cloudy or discoloured or the liquid has particles floating in it. **Do not** inspect the product through the plastic of the safety device.
    - Any part of the pre-filled syringe appears cracked or broken or any of the liquid has leaked out of the syringe.
    - The pre-filled syringe has been dropped. The pre-filled syringe may be broken even if you cannot see the break.
    - The needle cover is missing or not securely attached.
    - The expiration date printed on the label has passed.

    In all cases above discard the pre-filled syringe and use a new pre-filled syringe.

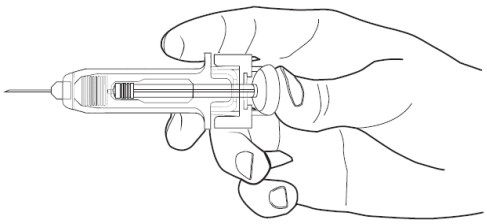
- Choose an injection site. Good sites are the top of the thigh and around the tummy (abdomen) but away from the navel. Vary the site from day to day.
- Wash your hands. Use an antiseptic swab on the injection site, to disinfect it.
- Hold the pre-filled syringe by the body of the needle guard with the covered needle pointing upward.
    - **Do not** hold by the plunger head, plunger or needle cover.
    - **Do not** pull back on the plunger at any time.
    - **Do not** remove the needle cover from the pre-filled syringe until you are ready to inject your medicine.
- Take the needle cover off the syringe by holding the barrel and pulling the needle cover straight off and away from your body carefully without twisting it. Throw away the needle cover. **Do not** recap the needle. **Do not** push the plunger, touch the needle or shake the syringe.



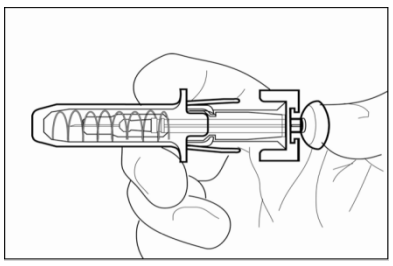
- Pinch a fold of skin between your thumb and index finger. **Do not** squeeze it.
- With your other hand, hold the pre-filled syringe like you would hold a pencil. Use a quick "dart-like" motion to insert the needle at an approximate 45 degree angle into the skin.



- Push the needle in fully. Your doctor or nurse may have shown you how to do this.
- Depress the plunger while grasping the finger flange until the entire dose has been given. The needle guard will NOT activate unless the ENTIRE dose has been given.



- When the plunger is pushed as far as it will go, take out the needle and let go of the skin.
- Let go of the plunger and allow the syringe to move up until the entire needle is guarded and locks into place.



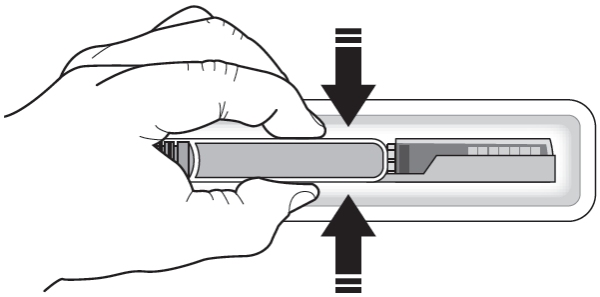
- When the needle is pulled out of your skin, there may be a little bleeding at the injection site. This is normal. You can press an antiseptic swab over the injection site for a few seconds after the injection.
- **Do not** try to replace the needle cover. Dispose of your used syringe in a sharps disposal (puncture-proof) container.
- **Never** put used syringes into your normal household waste bin.

How to inject yourself subcutaneously using a pre-filled syringe with a needle trap

Your syringe has a needle-trap attached to it which is designed to specifically help prevent accidental needle stick injuries following the proper administration of injectable medicines. It consists of a plastic needle "catcher" which is firmly attached to the syringe label. Together, these two components comprise the needle-trap (safety) feature.

The needle-trap requires specific actions by the user to "activate" it, which will render the needle harmless after the injection is administered.

- Remove the carton containing the pre-filled syringe from the refrigerator.
- Remove the blister tray containing the pre-filled syringe from the carton. When the carton contains blister trays with more than one pre-filled syringe, tear off the blister tray containing one pre-filled syringe along the perforated part, and return the rest of the blister trays containing pre-filled syringes to the carton and return the carton to the refrigerator.
- Open the blister tray containing the pre-filled syringe with needle trap by peeling away the cover after taking it out of the refrigerator.
- Grab the body of the syringe to remove the pre-filled syringe from the blister tray.

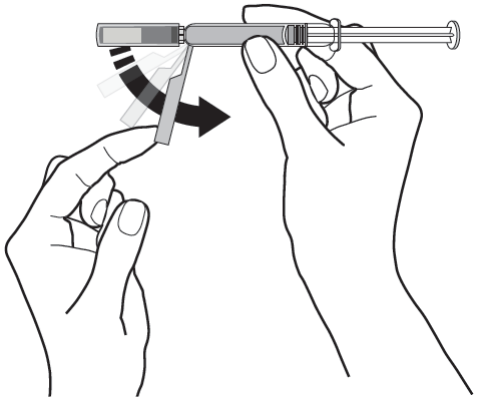


- **Do not** remove the needle cover from the pre-filled syringe until you are ready to inject your medicine.
- The liquid needs to come to room temperature. **Do not** remove the syringe's needle cover while allowing the pre-filled syringe to reach room temperature.
- Check the syringe, to make sure it is the right dose, has not passed its expiry date, is not damaged, and the liquid is clear and not frozen.
- **Do not use the pre-filled syringe if:**
  - The carton is open or damaged.
  - The medicine is cloudy or discoloured or the liquid has particles floating in it.
  - Any part of the pre-filled syringe appears cracked or broken or any of the liquid has leaked out of the syringe.
  - The pre-filled syringe has been dropped. The pre-filled syringe may be broken even if you cannot see the break.
  - The needle cover is missing or not securely attached.
  - The expiration date printed on the label has passed.

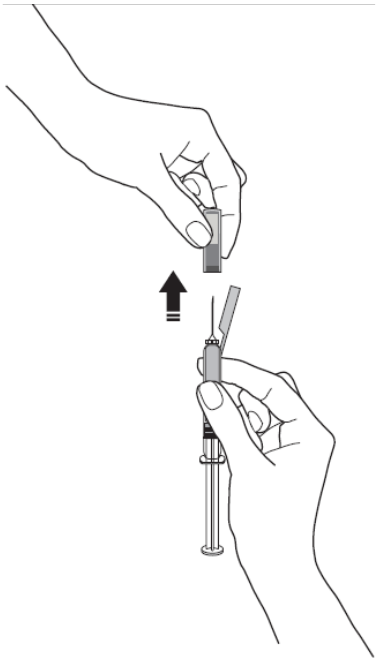
  In all cases above discard the pre-filled syringe and use a new pre-filled syringe.

- Choose an injection site. Good sites are the top of the thigh and around the tummy (abdomen) but away from the navel. Vary the site from day to day.
- Wash your hands. Use an antiseptic swab on the injection site, to disinfect it.

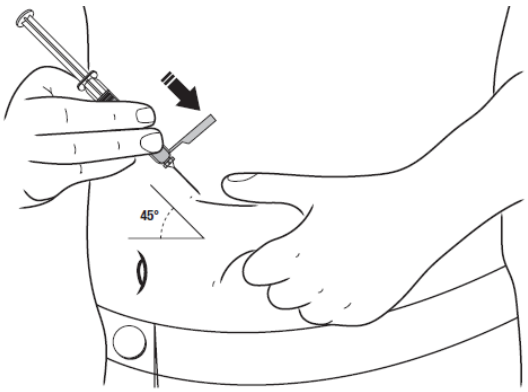
- Hold the pre-filled syringe by the body of the syringe with the covered needle pointing upward.
    - **Do not** hold by the plunger head, plunger or needle cover.
    - **Do not** pull back on the plunger at any time.
    - Grasp the tip of the plastic needle catcher and bend it away from the needle cover.



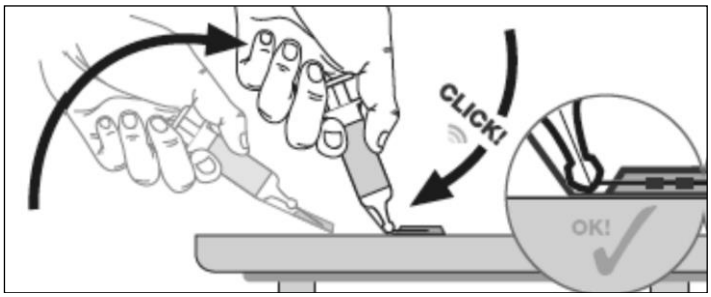
    - **Do not** remove the needle cover from the pre-filled syringe until you are ready to inject your medicine.
- Take the needle cover off the syringe by holding the barrel and pulling the needle cover straight off and away from your body carefully without twisting it. Throw away the needle cover. **Do not** recap the needle. **Do not** push the plunger, touch the needle or shake the syringe.



- Pinch a fold of skin between your thumb and index finger. **Do not** squeeze it.
- With your other hand, hold the pre-filled syringe like you would hold a pencil. Use a quick "dart-like" motion to insert the needle at an approximate 45 degree angle into the skin.



- Push the needle in fully. Your doctor or nurse may have shown you how to do this.
- Push the plunger with your thumb as far as it will go to inject the entire amount of liquid. Push it slowly and evenly, keeping the skin fold pinched.
- When the plunger is pushed as far as it will go, take out the needle and let go of the skin.
- Place the plastic catcher of the needle-trap against a hard, stable surface and with one hand pivot the syringe barrel upward against the needle forcing the needle into the catcher where it locks in place (an audible 'click" is heard when the needle is locked in the catcher). Continue bending the needle until the syringe exceeds a 45 degree angle with the flat surface to render it permanently unusable.



- When the needle is pulled out of your skin, there may be a little bleeding at the injection site. This is normal. You can press an antiseptic swab over the injection site for a few seconds after the injection.
- **Do not** try to replace the needle cover. Dispose of your used syringe in a sharps disposal (puncture-proof) container.
- **Never** put used syringes into your normal household waste bin.

If you use more Retacrit than you should

Tell the doctor or nurse immediately if you think too much Retacrit has been injected. Side effects from an overdose of Retacrit are unlikely.

If you forget to use Retacrit

Make the next injection as soon as you remember. If you are within a day of your next injection, forget the missed one and carry on with your normal schedule. Do not double up the injections to make up for a forgotten dose.

If you are a patient with hepatitis C and you receive interferon and ribavirin

You should discuss this with your doctor because a combination of epoetin zeta with interferon and ribavirin has led to a loss of effect and development of a condition called pure red cell aplasia (PRCA), a severe form of anaemia, in rare cases. Retacrit is not approved in the management of anaemia associated with hepatitis C.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor or nurse immediately if you notice any of the effects in this list.

Serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported in association with epoetin treatment. These can appear as reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms. Stop using Retacrit if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.

Very common: may affect more than 1 in 10 people.
- **Diarrhoea**
- **Feeling sick in your stomach**
- **Vomiting**
- **Fever**
- **Respiratory tract congestion**, such as stuffy nose and sore throat, has been reported in patients with kidney disease not yet on dialysis.

Common: may affect up to 1 in 10 people.
- **Increased blood pressure. Headaches**, particularly sudden, stabbing migraine-like headaches, **feeling confused or having fits** may be signs of a sudden increase in blood pressure. This requires urgent treatment. Raised blood pressure may require treatment with medicines (or adjustment to any medicines you already take for high blood pressure).
- **Blood clots** (including deep vein thrombosis and embolism) that may require urgent treatment. You may have **chest pain, breathlessness, and painful swelling and redness, usually in the leg** as symptoms.
- **Cough**
- **Skin rashes, which may result from an allergic reaction.**
- **Bone or muscle pain**
- **Flu-like symptoms**, such as headache, aches and pains in the joints, feeling of weakness, chills, tiredness and dizziness. These may be more common at the start of treatment. If you have these symptoms during injection into the vein, a slower delivery of the injection may help to avoid them in the future.
- **Redness, burning and pain at the site of injection**
- **Swelling of the ankles, feet or fingers**
- **Arm or leg pain**

Uncommon: may affect up to 1 in 100 people.
- **High levels of blood potassium** which can cause abnormal heart rhythm (this is a very common side effect in patients on dialysis).
- **Fits**
- **Nose or airway congestion**
- **Allergic reaction**
- **Hives**

Rare: may affect up to 1 in 1 000 people.
- **Symptoms of pure red cell aplasia (PRCA)**

  PRCA means the bone marrow does not make enough red blood cells. PRCA causes **sudden and severe anaemia. The symptoms are:**
  - **unusual tiredness,**

- **feeling dizzy,**
- **breathlessness.**

PRCA has been very rarely reported mostly in patients with kidney disease after months to years of treatment with Retacrit and other products that stimulate red blood cell production.

- An increase in levels of small blood cells (called platelets), which are normally involved in the formation of a blood clot may occur, particularly when starting treatment. Your doctor will check on this.

- Severe allergic reaction that may include:
  - a swollen face, lips, mouth, tongue or throat
  - difficulty swallowing or breathing
  - itchy rash (hives).

- Problem with the blood that may cause pain, dark coloured urine or increased sensitivity of the skin to sunlight (porphyria).

If you are receiving haemodialysis:
- **Blood clots** (thrombosis) may form in your dialysis shunt. This is more likely if you have low blood pressure or if your fistula has complications.
- **Blood clots** may also form in your haemodialysis system. Your doctor may decide to increase your heparin dose during dialysis.

Tell your doctor or nurse immediately if you are aware of any of these effects, or if you notice any other effects while you are receiving treatment with Retacrit.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Retacrit

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box and on the label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C-8°C). You may take Retacrit out of the refrigerator and keep it at room temperature (up to 25°C) for no longer than 3 days. Once a syringe has been removed from the refrigerator and has reached room temperature (up to 25°C) it must either be used within 3 days or disposed of.

Do not freeze or shake.

Store in the original package in order to protect from light.

Do not use this medicine if you notice that the seal is broken or if the liquid is coloured or you can see particles floating in it. In the event of either being observed, discard the medicinal product.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Content of the pack and other information

What Retacrit contains

– The active substance is epoetin zeta (produced by recombinant DNA technology in Chinese Hamster Ovary (CHO) cell line).

Retacrit 1 000 IU/0.3 mL solution for injection in pre-filled syringe

1 pre-filled syringe with 0.3 mL solution for injection contains 1 000 international units (IU) epoetin zeta (recombinant human erythropoietin). The solution contains 3 333 IU epoetin zeta per mL.

Retacrit 2 000 IU/0.6 mL solution for injection in pre-filled syringe

1 pre-filled syringe with 0.6 mL solution for injection contains 2 000 international units (IU) epoetin zeta (recombinant human erythropoietin). The solution contains 3 333 IU epoetin zeta per mL.

Retacrit 3 000 IU/0.9 mL solution for injection in pre-filled syringe

1 pre-filled syringe with 0.9 mL solution for injection contains 3 000 international units (IU) epoetin zeta (recombinant human erythropoietin). The solution contains 3 333 IU epoetin zeta per mL.

Retacrit 4 000 IU/0.4 mL solution for injection in pre-filled syringe

1 pre-filled syringe with 0.4 mL solution for injection contains 4 000 international units (IU) epoetin zeta (recombinant human erythropoietin). The solution contains 10 000 IU epoetin zeta per mL.

Retacrit 5 000 IU/0.5 mL solution for injection in pre-filled syringe

1 pre-filled syringe with 0.5 mL solution for injection contains 5 000 international units (IU) epoetin zeta (recombinant human erythropoietin). The solution contains 10 000 IU epoetin zeta per mL.

Retacrit 6 000 IU/0.6 mL solution for injection in pre-filled syringe

1 pre-filled syringe with 0.6 mL solution for injection contains 6 000 international units (IU) epoetin zeta (recombinant human erythropoietin). The solution contains 10 000 IU epoetin zeta per mL.

Retacrit 8 000 IU/0.8 mL solution for injection in pre-filled syringe

1 pre-filled syringe with 0.8 mL solution for injection contains 8 000 international units (IU) epoetin zeta (recombinant human erythropoietin). The solution contains 10 000 IU epoetin zeta per mL.

Retacrit 10 000 IU/1 mL solution for injection in pre-filled syringe

1 pre-filled syringe with 1 mL solution for injection contains 10 000 international units (IU) epoetin zeta (recombinant human erythropoietin). The solution contains 10 000 IU epoetin zeta per mL.

Retacrit 20 000 IU/0.5 mL solution for injection in pre-filled syringe

1 pre-filled syringe with 0.5 mL solution for injection contains 20 000 international units (IU) epoetin zeta (recombinant human erythropoietin). The solution contains 40 000 IU epoetin zeta per mL.

Retacrit 30 000 IU/0.75 mL solution for injection in pre-filled syringe

1 pre-filled syringe with 0.75 mL solution for injection contains 30 000 international units (IU) epoetin zeta (recombinant human erythropoietin). The solution contains 40 000 IU epoetin zeta per mL.

Retacrit 40 000 IU/1 mL solution for injection in pre-filled syringe

1 pre-filled syringe with 1 mL solution for injection contains 40 000 international units (IU) epoetin zeta (recombinant human erythropoietin). The solution contains 40 000 IU epoetin zeta per mL.

The other ingredients are disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate, sodium chloride (see section 2 "Retacrit contains sodium"), calcium chloride dihydrate, polysorbate 20 (E432) (see section 2 "Retacrit contains polysorbate 20"), glycine, leucine, isoleucine, threonine, glutamic acid, phenylalanine (see section 2 "Retacrit contains phenylalanine"), water for injections, sodium hydroxide (pH adjuster), hydrochloric acid (pH adjuster).

What Retacrit looks like and contents of the pack

Retacrit is presented as a clear and colourless solution for injection in a pre-filled syringe with a fixed injection needle.

The pre-filled syringes contain between 0.3 and 1 mL solution, depending on the content of epoetin zeta (see "What Retacrit contains").

One pack contains 1, 4 or 6 pre-filled syringes with or without a needle guard or needle-trap device. Multipacks contain 4 (4 x 1) or 6 (6 x 1) pre-filled syringes.

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