EPREX® PREFILLED SYRINGES

(Epoetin alfa (rch))

Consumer Medicine Information

WARNING FOR CANCER PATIENTS: use of medicines like EPREX that stimulate red blood cell production during chemotherapy has been associated with increased risk of death in some studies. Your doctor should only use EPREX to treat your anaemia if it is caused by chemotherapy and blood transfusions are not an appropriate treatment option.

What is in this leaflet

This leaflet answers some common estions about EPREX prefilled syringes. 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.

Current and updated information about benefits and side effects of EPREX is contained in this leaflet.

Your doctor has weighed the risks of you using EPREX against the benefits this medicine is expected to have for you.

If you have any concerns about using EPREX ask your doctor or pharmacist.

It is important that you read this leaflet.

Keep this leaflet with your medicine.

What EPREX is used for

EPREX prefilled syringes contain the active ingredient epoetin alfa, a protein that stimulates bone marrow to produce more red blood cells.

Red blood cells are responsible for carrying oxygen to all parts of your body. A decrease in the number of red blood cells can cause anaemia. Some symptoms of anaemia are tiredness, breathlessness when exercising, and feeling cold. Anaemia may have many causes, including decreased production of a hormone called erythropoietin by the kidneys due to kidney failure, or as a result of chemotherapy treatments for cancer. EPREX is virtually identical to your body's erythropoietin, and has a similar effect to naturally occurring erythropoietin in your body.

EPREX is used to treat the anaemia associated with kidney disease. If you have kidney disease, your kidney may not produce enough erythropoietin (necessary for red blood cell production) and your doctor may wish to correct this by prescribing EPREX. This medicine stimulates your bone marrow to produce more red blood cells, helping to treat your anaemia.

EPREX can also be used to treat anaemia if you are receiving chemotherapy for cancer and your doctor decides that a blood transfusion is not appropriate.

Doctors can also prescribe EPREX for mildly anaemic patients who are going to have surgery and donate blood before surgery, so that their own blood can be given to them during or after surgery. Because EPREX stimulates the production of red blood cells, a higher volume of blood can be taken from these patients.

EPREX can be used as an alternative to a blood transfusion in adult patients about to undergo major orthopaedic (bone) surgery where there is a potentially high risk from blood transfusion complications.

EPREX is not addictive.

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

Before you use EPREX

When you must not use it

Do not use EPREX

- If you have an allergy to EPREX or any of the ingredients. See Product Description at the end of this leaflet for a list of ingredients.

  Symptoms of an allergic or hypersensitivity reaction may include:

  - rash, itching or hives on the skin
  - shortness of breath, wheezing or difficulty breathing
  - swelling of the face, lips, tongue or other parts of the body
- If you have high blood pressure that is not properly controlled with blood pressure-lowering drugs.
- If you are a surgery patient who should not be given medicines to thin the blood.
- If you are due to have elective surgery and you have severe heart disease, disorders of the veins or arteries, or have recently had a heart attack or stroke.
- If you have been diagnosed with Pure Red Cell Aplasia (your bone marrow cannot produce enough red blood cells) after previous treatment with an erythropoietin product, including EPREX.
- If you cannot have transfusions with your own blood during or after surgery.

Do not use EPREX if the packaging is torn or shows signs of tampering.

Do not use EPREX beyond the expiry date (month and year) printed on the pack.

Before you start to use it

You must tell your doctor if you have or have had:

- high blood pressure
- heart disease (such as angina)
- disorders of blood circulation resulting in pins and needles or cold hands or feet or muscle cramps in the legs.
- blood clotting disorders
- seizures or epileptic fits
- cancer. If you are a cancer patient be aware that erythropoietins like EPREX may act as a growth factor and therefore in theory may affect the progression of your cancer. Please discuss this with your doctor.
- anaemia from other causes
- liver disease
- gout
- porphyria (a rare blood pigment disorder)
- an allergy to latex.

Also, tell your doctor if you are:

- pregnant or planning to become pregnant
- breastfeeding or wish to breastfeed.

In many women with severe kidney failure, their monthly periods may stop. In these women, erythropoietin may restart the monthly cycle. Before starting EPREX, you should discuss the need for contraception with your doctor.

Make sure you tell your doctor if you have any other medical problems since these may affect the use of EPREX.

If you have used EPREX or another erythropoietin in the past, and you lost the good response you were having, tell your doctor about this.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using or are given EPREX.

Your doctor will advise you whether or not to use EPREX or if you need to adjust the dose or adapt your treatment.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.

Iron is also a constituent of red blood cells. Therefore, iron supplements and other blood stimulating drugs may increase your response to EPREX treatment. Your doctor will decide whether you should take other medicines while using EPREX.

Using EPREX

How much to use:

- Your doctor will determine the correct dose of EPREX. EPREX injection is administered either into a vein (intravenously) or just under the skin (subcutaneously). After instruction, you can administer it under the skin yourself if you wish. Your doctor can discuss with you whether injection into the vein or under the skin is preferable.
- For patients with anaemia due to kidney failure, EPREX should be given intravenously, (into a vein or a tube that goes into a vein) if intravenous access is routinely available (haemodialysis patients). For patients not yet on dialysis and those on peritoneal dialysis EPREX can be administered subcutaneously. The usual starting dose is 50 IU/kg three times per week for adults and 25 IU/kg three times per week for children, after which the dose may be changed by your doctor as needed.
- For patients who are scheduled for surgery and who are not storing their own blood the usual dose is 300 IU/kg body weight for 10 days before surgery, on the day of surgery and for 4 days after. Alternatively a dose of 600 IU/kg may be administered weekly for 3 weeks before surgery and on the day of surgery. The subcutaneous route is used.
- For anaemic cancer patients receiving chemotherapy, the initial dose is 150 IU/kg three times per week. After 4 weeks your doctor will check your response and increase the dose to 300 IU/kg three times weekly if response has been insufficient. If at any stage EPREX has produced too many red cells, your doctor will stop the drug and later re-start it at a lower dose. The subcutaneous route is used.

Injecting EPREX under the skin yourself

At the start of your therapy, EPREX may be injected by medical or nursing staff. However, your doctor may decide that it is right for you to learn how to inject EPREX under the skin (subcutaneously) yourself. You will receive appropriate training for you to do this. Under no circumstances should you attempt to inject yourself unless you have been trained to do so.

Always use EPREX exactly as instructed by your doctor or nurse.

Only use EPREX if it has been stored correctly.

EPREX is for single use only.

EPREX should not be used, and should be discarded if:

- the seal is broken,
- the liquid is coloured or
- particles are in it,
- it may have been frozen, or
- there has been a refrigeration failure.

Any unused product or waste material should be disposed of in accordance with local requirements.

If EPREX is injected under the skin (subcutaneously), the amount injected is not normally more than one millilitre (1 mL) in a single injection.

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

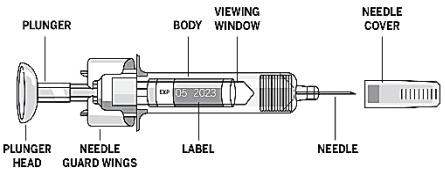
Only use EPREX if the solution is clear and colourless.

Do not shake EPREX prefilled syringes.

Prolonged vigorous shaking may damage EPREX. If EPREX has been shaken vigorously, don't use it.

How to inject EPREX under the skin

The pre-filled syringes are fitted with the PROTECS™ needle guard device to help prevent needle stick injuries after use. This is indicated on the packaging.



- **Take a syringe out of the refrigerator.**

  The liquid needs to come to room temperature. This usually takes between 15 to 30 minutes. Do not remove the syringe's needle cover while allowing it 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.

- **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, needle guard wings, 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 EPREX.**

- **Take the needle cover off the syringe by holding the body and pulling the needle cover off carefully without twisting it.**

  Don't push the plunger, touch the needle or shake the syringe.

  Do not touch the needle guard wings to prevent prematurely covering the needle with the needle guard.

- **Pinch a fold of skin**

  between your thumb and index finger. Don't squeeze it.

- **Push the needle in fully.**

- **Push the plunger with your thumb as far as it will go to inject all of the liquid.**

  Push it slowly and evenly, keeping the skinfold pinched. The needle guard will not activate unless the entire dose is given. You may hear a click when the needle guard has been activated.

- **When the plunger is pushed as far as it will go,**

  take out the needle and let go of the skin.

- **Slowly take your thumb off the plunger.**

  Allow the syringe to move up until the entire needle is covered by the needle guard.

- **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.

- **Dispose of your used syringe**

  in a safe container.

Only take one dose of EPREX from each syringe. If any liquid remains in the syringe after an injection, the syringe should be properly disposed of, not reused. EPREX prefilled syringes do not contain preservatives.

Therefore, once a syringe has been opened, any remaining solution must be discarded.

If you do not understand the instructions provided with this medicine, ask your doctor or pharmacist for help.

If you forget to use it

- Administer your dose as soon as you remember, and then continue to use it as you would normally.

- Do not administer a double dose to make up for the dose you missed.

If you have missed more than one dose, or are not sure what to do, check with your doctor or pharmacist.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you have used too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre for advice, or go to Accident and Emergency at your nearest hospital.

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

Poisons Information Centre telephone numbers:

- Australia: 13 11 26
- New Zealand: 0800 POISON or 0800 764 766

Keep these telephone numbers handy.

While you are using EPREX

Things you must do

- Always follow your doctor's instructions carefully.

If you are receiving dialysis treatment when you begin treatment with EPREX, your dialysis regimen may need to be adjusted. Your doctor will decide this.

You will need to have regular blood tests while you are using EPREX to see how you respond to treatment with EPREX. Your doctor will order regular blood tests to ensure that your medicine is continuing to work properly. If your haemoglobin levels are above 120 g/L, discuss reducing your EPREX dose with your doctor.

Your doctor will need to monitor your blood pressure regularly, especially at the beginning of treatment.

An increase in levels of small cells (called platelets) in your blood may occur, particularly when starting haemodialysis treatment.

- Tell your doctor if you become pregnant while using EPREX.
- If you experience a severe skin reaction, a rash, which may be severe, may cover your whole body and can also include blisters or areas of skin coming off, stop using EPREX and call your doctor or get medical help right away.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are using EPREX.
- If you become increasingly tired, dizzy or breathless, you should talk to your doctor at once. Your doctor can decide whether EPREX is not working properly for you and will end the treatment if necessary.
- If you are due to have major surgery, your doctor will give you a medicine to reduce the risk of abnormal blood clotting.
- Remember to tell your doctor if you received EPREX or another erythropoietin-like medicine in the past and you experienced a worsening in your anaemia.
- Take special care with other products that stimulate red blood cell production: EPREX is one of a group of products that stimulate the production of red blood cells like the human protein erythropoietin does. If you are given a product in this group other than the one prescribed by your doctor during your treatment, speak to your doctor before using it. It is important that you continue to use the same product in the group unless your doctor says otherwise.

Things you must not do

- Do not use EPREX to treat any other complaint unless your doctor says so.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Side Effects

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

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you experience any of the following

- Nausea, vomiting or diarrhoea
- Cough or congested airways such as stuffy nose and sore throat
- Flu-like symptoms such as dizziness, drowsiness, fever, chills, headache, muscle and joint pain and weakness.
- Redness, burning and pain at the site EPREX is given.
- Swelling of the lower legs or hands.

Tell your doctor immediately if you notice any of the following, as you may need urgent medical care

- Severe, sudden, stabbing migraine-like headaches.
- Seizures, confusion or epileptic fits.
- Raised blood pressure, which may require treatment with drugs or adjustment of the doses of drugs you already take for high blood pressure.
- Clotting of your blood in the haemodialysis system, or blockage of your fistula if you are on dialysis. There may be a need

to increase your heparin dose during dialysis.

- Chest pain, breathlessness, painful swelling in the leg that may be symptoms of a blood clot (thrombosis).
- Skin rashes and accumulation of fluid under the skin of the eyelids (oedema), which may result from an allergic reaction.
- Signs of allergy such rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body.
- Sudden tiredness, dizziness or sudden shortness of breath.

  Your doctor will want to investigate this. These symptoms may be caused by a condition called pure red cell aplasia (PRCA). PRCA has been rarely reported after months to years of treatment with EPREX. PRCA means the absence of very young red blood cells in the bone marrow. If this condition develops, you suddenly lose the good response you have been having to EPREX. As the previous cases of PRCA occurred mainly with subcutaneous administration it is preferable that EPREX be administered intravenously whenever possible. Although PRCA is rare, you should be informed that if it develops, you would need to have regular blood transfusions to treat your anaemia, and EPREX would have to be stopped.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

After using EPREX

Storage

Store EPREX between 2°C and 8°C in the refrigerator. Do not freeze and protect from light. Immediately prior to use, EPREX may be stored in a room that stays below 25°C, for a maximum single period of seven days. Keep your medicine out of reach of children.

Do not store EPREX, or any other medicine, in the bathroom or near a sink. Do not leave medicines in the car or on windowsills. Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop using EPREX, or your medicine has passed its expiry date, ask your pharmacist what to do with any medicine that may be left over.

Product Description

What it looks like

EPREX injection is a clear, colourless solution in prefilled syringes of 1000 IU in 0.5 mL, 2000 IU in 0.5 mL, 3000 IU in 0.3 mL, 4000 IU in 0.4 mL, 5000 IU in 0.5 mL, 6000 IU in 0.6 mL, 8000 IU in 0.8 mL, 10000 IU in 1.0 mL, 20,000 IU in 0.5 mL, 30,000 IU in 0.75 mL and 40,000 IU in 1.0 mL. Each box contains 6 prefilled syringes (1 syringe for 40,000 IU).

Australian Registration numbers:

Phosphate buffered syringes:

EPREX 1000 0.5 mL

AUST R 65442

EPREX 2000 0.5 mL

AUST R 65443

EPREX 3000 0.3 mL

AUST R 65444

EPREX 4000 0.4 mL

AUST R 65445

EPREX 5000 0.5 mL

AUST R 76970

EPREX 6000 0.6 mL

AUST R 76971

EPREX 8000 0.8 mL

AUST R 76973

EPREX 10000 1.0 mL

AUST R 65446

EPREX 20000 0.5 mL

AUST R 73486

EPREX 30000 0.75 mL

AUST R 135069

EPREX 40000 1.0 mL

AUST R 73487

Ingredients

EPREX is the tradename in Australia and New Zealand for Epoetin alfa (rch) (r-HuEPO).

EPREX injection in prefilled syringes is stabilised with glycine (5 mg/mL) and polysorbate 80 (0.3 mg/mL). All formulations also contain sodium chloride at 1.7 - 5.8 mg, monobasic sodium phosphate dihydrate at 0.35 - 1.16 mg, dibasic sodium phosphate dihydrate at 0.67 - 2.22 mg, sodium citrate at less than 5 mmol and water for injections.

The prefilled syringes are fitted with the PROTECS™ needle guard device to help prevent needle stick injuries after use.

The needle cover of the prefilled syringe contains dry natural rubber (a derivative of latex).

EPREX does not contain lactose or gluten.

Sponsor

JANSSEN-CILAG Pty Ltd

1-5 Khartoum Road

Macquarie Park NSW 2113 Australia

Telephone: (02) 8875 3333

NZ Office: Auckland New Zealand

Telephone: 0800 800 806

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