

คำแนะนำในการใช้ยาภาษาอังกฤษสำหรับผู้ป่วย

EPREX® (Epoetin alfa)

SOLUTION FOR INJECTION in PRE-FILLED SYRINGES

WARNING: PURE RED BLOOD CELL APLASIA (PRCA)

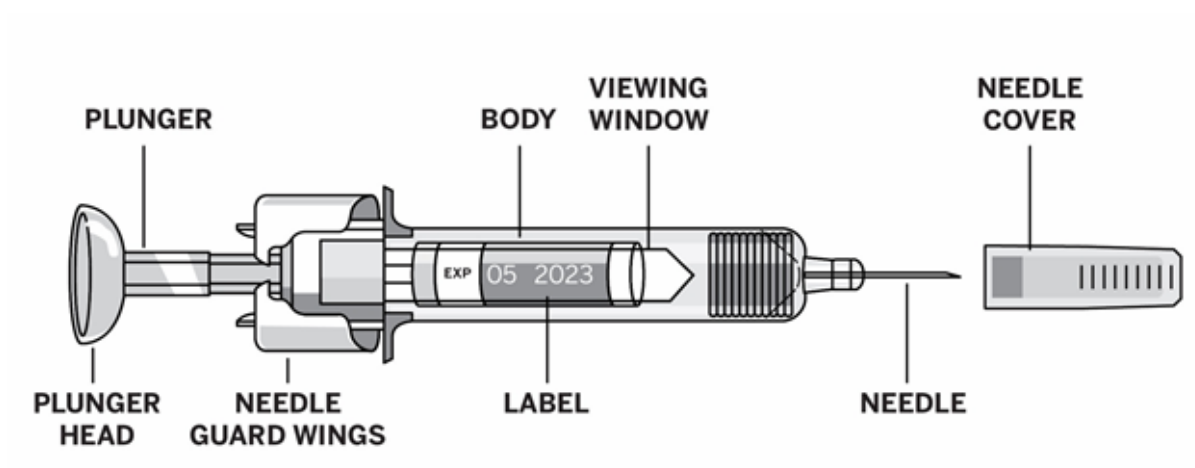
According to the increased incidence of antibody-mediated pure red blood cell aplasia (PRCA) in chronic renal failure patients who were administered Epoetin subcutaneously for long term treatment, as well as Hepatitis C patients who were treated with Epoetin, interferon and ribavirin as combination therapy.

For those chronic renal failure patients, who poorly responsive to ESA therapy and require transfusion, a reticulocyte count testing should be investigated. In case of reticulocyte index less than 20,000/microliters or less than 0.5% with normal platelets and white blood cells, the anti-erythropoietin antibodies and bone marrow testing should be performed to investigate the PRCA. Unless the test results are clear, the patient should be warned to discontinue the treatment with Epoetin including ESA therapy due to cross-reaction.

Instructions on how to inject EPREX subcutaneously yourself using a pre-filled syringe

When treatment starts, EPREX is usually injected by medical or nursing staff. Later, your doctor may suggest that you or your caregiver learn how to inject EPREX 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 EPREX exactly as instructed by your doctor or nurse.**
Only use EPREX if it has been stored correctly
- The product is for single use only.
- The product should not be used, and should be discarded if:
 - the seal is broken,
 - the liquid is colored 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 subcutaneously; the amount injected is not normally more than one milliliter (1 mL) in a single injection.
- EPREX is given alone and not mixed with other liquids for injection.
- Do not shake EPREX syringes. Prolonged vigorous shaking may damage the product. If the product has been shaken vigorously, don't use it.
- 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, plunger, 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 liquid.** Push it slowly and evenly, keeping the skin fold 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.

HOW TO STORE EPREX

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 the letters EXP. The expiry date refers to the last day of that month.

Store in a refrigerator 2°C-8°C (36°F to 46°F). You may take EPREX out of the refrigerator and keep it at room temperature (up to 25°C) for no longer than 7 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 7 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 colored 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 waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

FURTHER INFORMATION

What EPREX contains:

The active substance is: Epoetin alfa.

The other ingredients are: disodium phosphate dihydrate; glycine and water for injections; Polysorbate 80, sodium chloride, and sodium dihydrogen phosphate dihydrate.

What EPREX looks like and contents of the pack:

EPREX is presented as a solution for injection in a pre-filled syringe. The pre-filled syringes are fitted with the PROTECS™ needle guard device. EPREX is a clear, colorless solution.

EPREX is supplied in type I glass prefilled syringes with FluroTec®-coated rubber stoppers.

Manufactured by

Cilag AG, Schaffhausen, Switzerland

Market Authorization numbers and Date of Authorization

Product name	Market authorization number	Date of Authorization
EPREX (Prefilled syringe 2,000 IU/0.5 mL)	1C 7/54 (B)	2 May 2011
EPREX (Prefilled syringe 40,000 IU/mL)	1C 8/54 (B)	2 May 2011
EPREX (Prefilled syringe 10,000 IU/mL)	1C 9/54 (B)	2 May 2011

Version Number

CPPI version 10-Sep-2021_Remove long PIL

Imported by

Janssen-Cilag Ltd. Bangkok, Thailand

To report Suspected Adverse Reactions, please contact us at aepqcjacth@its.jnj.com

For any product information, please contact us at *medinfosea@its.jnj.com*

Please see full prescribing information at <https://ndi.fda.moph.go.th>