

Patient Information
EPOGEN[®] (EE – PO – JEN)
Epoetin Alfa
For Injection

This patient package insert contains information and directions for patients (and their caregivers) whose doctor has determined that they may receive injections of EPOGEN[®] (EE-PO-JEN) at home. Please read it carefully. This patient package insert does not include all information about EPOGEN[®] and does not replace talking with your doctor. You should discuss any questions about treatment with EPOGEN[®] with your doctor. Only your doctor can prescribe EPOGEN[®] and determine if it is right for you.

What is the most important information I should know about EPOGEN[®]?

EPOGEN[®] can cause serious side effects:

Chronic kidney failure patients:

- If your hemoglobin is kept too high, you have an increased chance of heart attack, stroke, heart failure, blood clots, and death. Your doctor should try to keep your hemoglobin between 10 and 12 g/dL.

Cancer patients:

- You may have an increased chance of dying sooner or your tumor (cancer) may grow faster if you take this drug.
- Your doctor should use the lowest dose of EPOGEN[®] needed to help you avoid red blood cell transfusions.
- Once you have completed your chemotherapy course, EPOGEN[®] treatment should be stopped.

All patients:

- EPOGEN[®] treatment increases your chance of a blood clot. If you are scheduled for surgery, your doctor may prescribe a blood thinner to prevent blood clots.
- Blood clots can form at your vascular access if you are receiving hemodialysis. Call your doctor or dialysis center if you think your access is blocked.
- Blood clots can form in blood vessels (veins) in your leg (venous thrombosis). Blood clots may move from the legs to the lungs and block the blood circulation in the lungs (pulmonary embolus).

Call your doctor right away if you experience any of the following symptoms of a blood clot, while taking EPOGEN®:

- chest pain
- shortness of breath
- pain in the legs with or without swelling

You will be asked to have blood tests that will check the number of red blood cells your body is producing. The blood tests will see if EPOGEN® is working and if your hemoglobin level is getting too high. Your doctor may refer to the results of your blood tests as hemoglobin and hematocrit. The amount of time it takes to reach the red blood cell level that is right for you, and the dose of EPOGEN® needed to make the red blood cell level rise, is different for each person. You may need EPOGEN® dose adjustments before you reach your correct dose of EPOGEN® and the correct dose may change over time. It is important to keep all appointments for blood tests to allow your doctor to adjust the dosage of EPOGEN® as needed.

Please also read ‘**What are the possible side effects of EPOGEN®?**’ below.

What is EPOGEN®?

EPOGEN® is a man-made form of the protein human erythropoietin (ee-rith-row-po-eh-tin). EPOGEN® works by stimulating your bone marrow to make red blood cells. After two to six weeks of treatment, your red blood cell counts may increase.

EPOGEN® may be used to treat your anemia (a lower than normal number of red blood cells) if it is caused by:

- chronic kidney failure (you may or may not be on dialysis)
- chemotherapy used to treat cancer
- a medicine called zidovudine (AZT), used to treat HIV infection

EPOGEN® may be given prior to certain types of operations where the chances of significant blood loss and blood transfusions is high, in order to reduce the need for blood transfusions during and after surgery.

EPOGEN® does not improve symptoms of anemia, quality of life, fatigue, or patient well-being for patients with cancer or with HIV.

EPOGEN® increases hemoglobin levels and improves exercise tolerance and physical functioning in chronic kidney failure patients on dialysis.

Before receiving EPOGEN®, you should talk with your doctor about the benefits and risks of EPOGEN®.

Who should not take EPOGEN®?

You should not take EPOGEN® if you have:

- High blood pressure that is not controlled (uncontrolled hypertension).

- Antibodies to EPOGEN[®] or other erythropoietins.

Talk to your doctor if you are not sure if you have these conditions or if you have any questions about this information.

What should I tell my doctor before taking EPOGEN[®]?

Tell your doctor about all your health conditions and all the medicines you take, including prescription and over-the-counter medicines, vitamins, supplements, and herbals. Be sure to tell your doctor if you have:

- Heart disease
- High blood pressure
- Any history of seizures or strokes
- Blood disorders (such as sickle cell anemia, blood clotting disorders)

Tell your doctor if you are:

- Pregnant or nursing
- Planning to become pregnant

EPOGEN[®] has not been studied in pregnant women and its effects on developing babies are not known. It is also not known if EPOGEN[®] can pass into human breast milk.

Talk to your doctor if you are not sure if you have these conditions or if you have any questions about this information.

Your doctor may monitor your blood pressure and the amount of iron in your blood before you start EPOGEN[®] and while you are taking EPOGEN[®]. You or your caregiver may also be asked to monitor your blood pressure every day and to report any changes. When the number of red blood cells increases, your blood pressure may also increase, so your doctor may prescribe new or more blood pressure medicine. You may be asked to have certain blood tests, such as hemoglobin, hematocrit or blood iron levels. Also, your doctor may prescribe iron for you to take. Follow your doctor's orders.

What are other possible side effects of EPOGEN[®]?

EPOGEN[®] may cause serious side effects. See "**What is the most important information I should know about EPOGEN[®]?**"

Other side effects of EPOGEN[®] include:

- Increased blood pressure; your doctor or caregiver may monitor your blood pressure more frequently.

- Infections
- Cough
- Chest pain
- Antibodies against EPOGEN[®] that can block or reduce your body's ability to make red blood cells. If you experience unusual tiredness and lack of energy, **call your doctor**.
- Redness, swelling, pain, or itching at the site of injection. If you notice any signs of redness, swelling, or itching at the site of injection, talk to your doctor.
- Serious allergic reactions. These reactions can cause a rash over the whole body, shortness of breath, wheezing, a drop in blood pressure, swelling around the mouth or eyes, fast pulse, or sweating. If at any time a serious allergic reaction occurs, **stop using EPOGEN[®] and call your doctor or emergency medical personnel immediately (for example, call 911)**.

The most common side effects you may have when taking EPOGEN[®] are:

- Increased blood pressure
- Headache
- Body aches
- Diarrhea
- Nausea
- Vomiting
- Swelling in your legs and arms
- Shortness of breath
- Fever

Some side effects are more common depending on the reasons for which you are taking EPOGEN[®]. Talk to your doctor for more information about side effects. Make sure to report any side effects to your doctor.

EPOGEN[®] has other side effects that are not listed here. For a complete list, talk to your doctor.

Call your doctor right away if:

- You take more than the amount prescribed.
- You are currently taking EPOGEN[®] and experience any of these symptoms which may be a sign of a serious problem:
 - Unusual tiredness and lack of energy
 - Redness, swelling, pain, or itching at the site of injection and spreading rash over the whole body, shortness of breath, wheezing, a drop in blood pressure, swelling around the mouth or eyes, fast pulse, or sweating
 - Convulsion, confusion, dizziness, loss of consciousness
 - Increased blood pressure, chest pain, irregular heartbeats
 - Stroke, chest pain, shortness of breath, or pain with or without swelling in the legs
 - Blood clots in your hemodialysis vascular access port

How should I take EPOGEN®?

After your doctor has determined that you, as a home dialysis patient, or your caregiver can administer EPOGEN® at home, ***always follow the instructions of your doctor concerning the dose, how to administer and how often to administer EPOGEN®.*** Ask your doctor what to do if you miss a dose of EPOGEN®.

Always keep an extra syringe and needle on hand.

When you receive your EPOGEN® from the dialysis center, doctor's office or pharmacy, always check to see that:

1. The name EPOGEN® appears on the carton and vial label.
2. You will be able to use EPOGEN® before the expiration date stamped on the package.

The EPOGEN® solution in the vial should always be clear and colorless. Do not use EPOGEN® if the contents of the vial appear discolored or cloudy, or if the vial appears to contain lumps, flakes, or particles. If the vial has been shaken vigorously, the solution may appear to be frothy and should not be used. Do not to shake the EPOGEN® vial before use.

Always use the correct syringe.

Your doctor has instructed you on how to give yourself the correct dosage of EPOGEN®. This dosage will usually be measured in Units per milliliter or cc's. It is important to use a syringe that is marked in tenths of milliliters (for example, 0.2 mL or cc). Using the wrong syringe can lead to a mistake in your dose, and you may receive too much or too little EPOGEN®. Too little EPOGEN® may not be effective in increasing the number of red blood cells. Too much EPOGEN® may lead to serious problems because too many red blood cells are being produced (a hemoglobin or hematocrit that is too high).

Only use disposable syringes and needles. Use the syringe once and dispose of it as instructed by your doctor.

Single Use Vials-S

If you have been prescribed EPOGEN® vials for single use, your vial will have a capital "S" with a number next to it identifying the concentration of EPOGEN® in the vial, printed in a colored dot on the front left side of the label (for example, "S2" identifies a single use vial with 2000 Units/mL). Single use means the vial cannot be used more than once, and any unused portion of the vial should be discarded as directed by your doctor.

Multidose Use Vials-M

If you have been prescribed EPOGEN® Multidose vials, your vial will have a capital "M" with a number under it identifying the concentration of EPOGEN® in the vial, printed in a colored dot on the front left side of the label (for example, "M10" identifies a Multidose vial with 10,000 Units/mL). Multidose EPOGEN® can be used to inject multiple doses as prescribed by your doctor, and may be stored between doses in the refrigerator (but not the freezer) for up to 21 days. Follow your doctor's or dialysis center's instructions on what to do with the used vials.

IMPORTANT: TO HELP AVOID CONTAMINATION AND POSSIBLE INFECTION, FOLLOW THESE INSTRUCTIONS EXACTLY.

Preparing the dose:

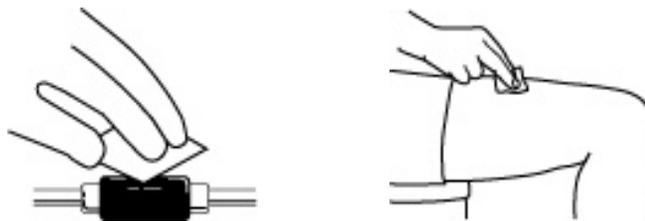
1. Remove the vial of EPOGEN[®] from the refrigerator and allow it to reach room temperature. Do not leave the vial in direct sunlight. Each EPOGEN[®] vial is designed to be used only once, unless you are using a Multidose vial. Do not shake EPOGEN[®]. Assemble the other supplies you will need for your injection (vial; syringe; alcohol antiseptic wipes and a container for disposing the needle).



2. Check the date on the EPOGEN[®] vial to be sure that the drug has not expired.
3. Wash your hands thoroughly with soap and water before preparing the medication.



4. Wipe off the venous port of the hemodialysis tubing with an antiseptic swab or cleanse the skin with an antiseptic swab where the injection is to be made. Be careful not to touch the area that has been wiped with the antiseptic.



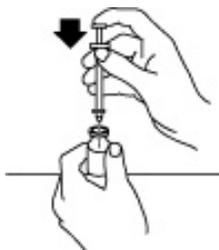
5. Flip off the protective cap but do not remove the gray rubber stopper. Wipe the top of the gray rubber stopper with an antiseptic swab.



- Using a syringe and needle that has been ordered by your doctor, carefully remove the needle cover. Then, draw air into the syringe by pulling back on the plunger. The amount of air should be equal to your EPOGEN[®] dose/volume.



- With the vial on a flat work surface, put the needle through the gray rubber stopper of the EPOGEN[®] vial.
- Push the plunger in to discharge air into the vial. The air injected into the vial will allow EPOGEN[®] to be easily withdrawn into the syringe.



- Turn the vial and syringe upside down in one hand. Be sure the tip of the needle is in the EPOGEN[®] solution. Your other hand will be free to move the plunger. Pull back on the plunger slowly to draw the correct dose of EPOGEN[®] into the syringe.

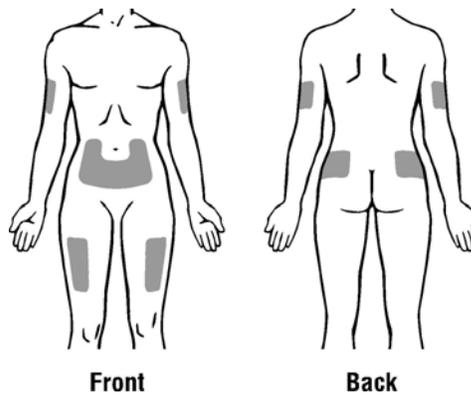


- Check for air bubbles. A small amount of air is harmless, but too large an air bubble will reduce the EPOGEN[®] dose. To remove air bubbles, gently tap the syringe with your fingers to move the air bubbles to the top of the syringe, then use the plunger to push the solution and the air back into the vial. Keeping the tip of the needle in the EPOGEN[®] solution, refill the syringe with your correct dose of EPOGEN[®].
- Double-check that you have the correct dose in the syringe. Remove the needle from the vial. Do not lay the syringe down or allow the needle to touch anything.

Injecting the dose:

EPOGEN[®] can be injected into your body using two different ways as described below. Make sure you discuss with your doctor and understand which way is best for you. In patients on hemodialysis, the IV route is recommended.

1. **SUBCUTANEOUS Route:** EPOGEN[®] can be injected directly into a layer of fat under your skin. This is called a subcutaneous injection. When receiving subcutaneous injections, always change the site for each injection as directed by your doctor. You may wish to record and track the site where you have injected. Do not inject EPOGEN[®] into an area that is tender, red, bruised, hard, or has scars or stretch marks. Recommended sites for injection are presented in the figure below, including the outer area of the upper arm, the abdomen (except for the two-inch area around the navel), the front of the middle thighs, and the outer area of the buttocks.



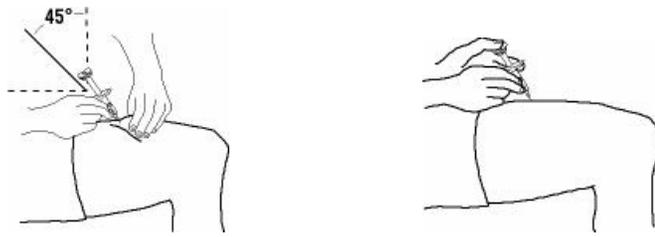
2. **INTRAVENOUS Route:** EPOGEN[®] can be injected in your vein through a special access port put in by your doctor. This type of EPOGEN[®] injection is called an intravenous injection. This route is usually for hemodialysis patients. If you have a dialysis vascular access, to make sure it is working, continue to check your access as your doctor or nurse has shown you. Be sure to let your healthcare provider know right away if you are having any problems, or if you have any questions.

Using the subcutaneous route:

1. With one hand, hold the area surrounding the cleaned skin either by spreading it or by pinching up a large area. Do not touch the cleansed area.



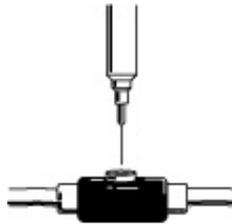
2. Double-check that the correct amount of EPOGEN[®] is in the syringe.
3. Hold the syringe with the other hand, as you would a pencil, insert the needle into the skin at a 45-degree angle. Let go of the skin and pull the plunger back slightly. If blood comes into the syringe, do not inject EPOGEN[®], as the needle has entered a blood vessel; withdraw the syringe, clean a new area, follow steps 1 and 2 and inject at a different site. If blood does not enter the syringe, inject the EPOGEN[®] by pushing the plunger all the way down.



4. Pull the needle straight out of the skin and immediately press the antiseptic swab over the injection site for several seconds.

Using the intravenous injection route (hemodialysis patients):

1. Insert the needle of the syringe into the clean venous port and inject the EPOGEN[®].



How should I dispose of syringes and needles?

Remove the syringe and dispose of the whole unit **WITHOUT RECAPPING THE NEEDLE**. Use the disposable syringe only once. Dispose of syringes and needles as directed by your doctor, by following these simple steps:

- Place all used needles and syringes in a labeled hard-plastic container with a screw-on-cap, or a labeled metal container with a plastic lid, such as a coffee can properly labeled as to content. If a metal container is used, cut a small hole in the plastic lid and tape the lid to the metal container. If a hard-plastic container is used, always screw the cap on tightly after each use. When the container is full, tape around the cap or lid, and **dispose of according to your doctor's instructions**.
- Do not use glass or clear plastic containers, or any container that will be recycled or returned to a store.
- ALWAYS store the container out of the reach of children.
- Please check with your doctor, nurse, or pharmacist for other suggestions. There may be special state and local laws that they will discuss with you. **DO NOT THROW THE CONTAINER IN YOUR HOUSEHOLD TRASH.**

How should I store EPOGEN®?

EPOGEN® should be stored in the refrigerator, but NEVER in the freezer. Do not use a vial of EPOGEN® that has been frozen. Do not leave the vial in direct sunlight. If you have any questions about EPOGEN® that has been exposed to temperature extremes, be sure to check with your doctor. When traveling, transport EPOGEN® in its original carton in an insulated container with a coolant such as blue ice. To avoid freezing, make sure the EPOGEN® vial does not touch the coolant. Once you arrive, your EPOGEN® should be placed in a refrigerator as soon as possible.

General information about EPOGEN®

Doctors can prescribe medicines for conditions that are not in this leaflet. Use EPOGEN® only for what your doctor prescribed. Do not give it to other people, even if they have the same symptoms that you have. It may harm them.

This leaflet gives the most important patient information about EPOGEN®. For more information, talk to your doctor or Healthcare provider. You can also visit www.epogen.com or call 1-800-77-AMGEN.

Active Ingredients: Epoetin alfa

Inactive Ingredients: All formulations include Albumin (human), sodium citrate, sodium chloride, and citric acid in water for injection. In addition, certain formulations may contain: benzyl alcohol, sodium phosphate monobasic monohydrate or sodium phosphate dibasic anhydrate.



Manufactured by:

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