MIRCERA®
methoxy polyethylene glycol-epoetin beta

USING MIRCERA® AT HOME

Instructions for Subcutaneous Injection

MIRCERA® (methoxy polyethylene glycol-epoetin beta) Injection, Single-Dose Prefilled Syringe

Indication: Mircera is a prescription medicine used to treat anemia. Mircera may be used to treat anemia if it is caused by chronic kidney disease (CKD). Mircera is used to reduce or avoid the need for red blood cell (RBC) transfusions.

Mircera may be used to treat CKD-related anemia in:

- adults who may or may not be on hemodialysis, **and**
- children ages 5 to 17 years on hemodialysis.

Mircera should not be used:

- in the treatment of anemia that is caused by cancer chemotherapy.
- in place of emergency treatment for anemia (RBC transfusions).

Mircera has not been proven to improve the quality of life, fatigue, or well-being.

Please see Important Safety Information including serious side effects on pages 13-15, full Prescribing Information, including Boxed WARNING, Medication Guide and Instructions for Use.

Before you begin

Read the Medication Guide that comes with Mircera for the most important information you need to know. The following instructions explain how to give yourself or another individual an injection of Mircera using the single-dose prefilled syringe as per new IFU. Be sure that you read, understand and follow these instructions before injecting a dose of Mircera, so that you are able to use the prefilled syringe correctly and safely.

Your healthcare provider should show you how to correctly prepare and inject Mircera using the single-dose prefilled syringe before you use it for the first time.

Ask your healthcare provider or pharmacist if you have any questions about Mircera.

When you receive your Mircera prefilled syringes, make sure that:

- The name Mircera appears on the pack.
- The pack is not damaged. **Do not** use Mircera if the prefilled syringe, the pack or the plastic tray containing the prefilled syringe appears to be damaged.
- The expiration date on the pack has not passed. **Do not use Mircera after the expiration date on the pack**.
- The strength (mcg/mL) on the Mircera pack is the same as the strength (mcg/mL) prescribed by your healthcare provider. Mircera prefilled syringes come in several different strengths measured in mcg/mL.

  Depending on your prescribed dose you may:
  - receive more than one strength of Mircera prefilled syringes.
  - need to give more than one injection to receive a complete dose.

Important information

- Only use Mircera prefilled syringes if you have been prescribed this medicine by your healthcare provider.
- Your healthcare provider may decide that you or a caregiver may give Mircera at home by an injection under your skin (subcutaneous) or by an intravenous injection. Your healthcare provider or nurse will train you how to prepare and inject Mircera properly. It is important that you **do not** try to give Mircera unless you or your caregiver has received training from your healthcare provider.
- Keep the Mircera prefilled syringe in the sealed pack until you are ready to use it.
- **Do not** use the syringe if the medicine is cloudy, hazy, or contains particles.
- **Do not** attempt to take the syringe apart.
- **Do not** hold or pull the prefilled syringe by the plunger.
- **Do not** remove the needle shield until you are ready to give an injection.
- **Do not** inject through clothing.
- **Do not** swallow the medicine in the syringe.
- **Do not** touch the activation guards before use (see Figure A). Touching them may cause the needle safety device to be released too early and make the prefilled syringe unusable.

Throw away (dispose of) the used Mircera prefilled syringe right away after use. Do not reuse a Mircera prefilled syringe or needle. See "Disposing of used prefilled syringes and needles" on page 12.

Please see Important Safety Information including serious side effects on pages 13-15, full Prescribing Information, including Boxed WARNING, Medication Guide and Instructions for Use.

How should I store Mircera?

- Store Mircera in the refrigerator between 36°F to 46°F (2°C to 8°C).
- If a refrigerator is not available, Mircera prefilled syringes can be stored at room temperature between 68°F to 77°F (20°C to 25°C) for no more than 30 days.
- **Do not freeze Mircera. Do not** use Mircera that has been frozen.
- Keep Mircera in the original package.
- Protect Mircera from light.
- **Do not** shake Mircera.

Keep Mircera and all medicines out of the reach of children.

What is included in my Mircera prefilled syringe pack?

Materials INCLUDED in the Mircera prefilled syringe pack (Figure A)

- A prefilled syringe containing Mircera
- A separate injection needle

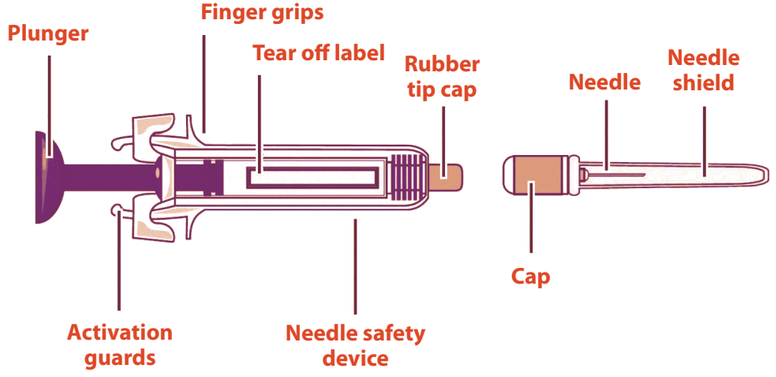

Figure A

Materials NOT INCLUDED in the Mircera prefilled syringe pack (Figure B)

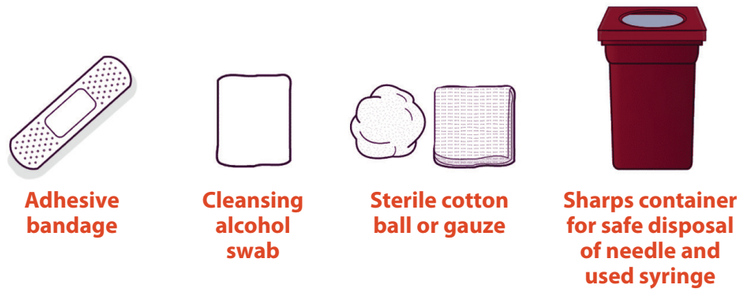

Figure B

Preparing for an injection

IMPORTANT: Follow these instructions exactly to help avoid infections.

1. Gather all of the materials you will need for an injection on a clean, well-lit, flat work surface such as a table.
2. **Allow the syringe to reach room temperature:** Carefully remove your prescribed pack of Mircera from the refrigerator (see Figure C).
   - Keep the prefilled syringe in the pack to protect it from light and allow it to reach room temperature for about 30 minutes. If the prefilled syringe does not reach room temperature, this could cause your injection to feel uncomfortable, and it may be difficult to push (depress) the plunger.

   Do not *warm up the prefilled syringe in any other way.*

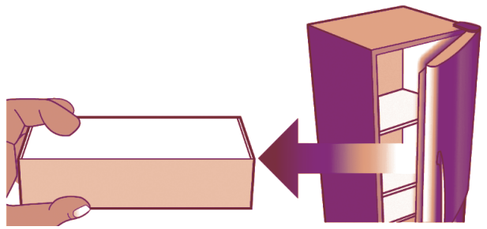

Figure C

3. **Open the pack** and remove the plastic tray containing the Mircera prefilled syringe without peeling back the protective film (see Figure D).

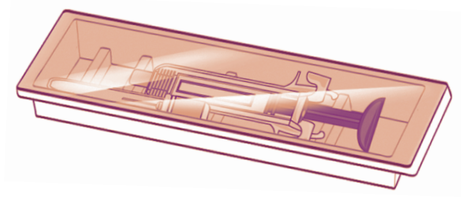

Figure D

4. **Wash your hands** well with soap and warm water (see Figure E).

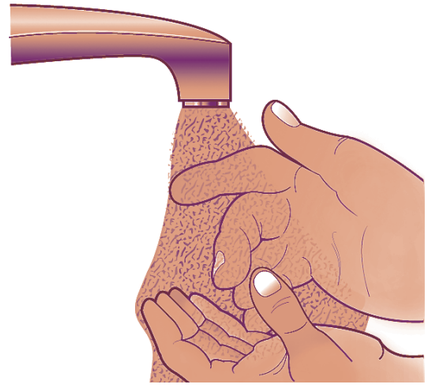

Figure E

5. **Remove and inspect the prefilled syringe.** Open the plastic tray by peeling back the protective film. Remove the prefilled syringe by holding the syringe by the device body (see Figure F). **Do not** touch the activation guards.
   - Only handle the prefilled syringe by the device body. Touching the activation guards could cause the needle safety device to be released too early.
   - Remove the needle from the plastic tray.

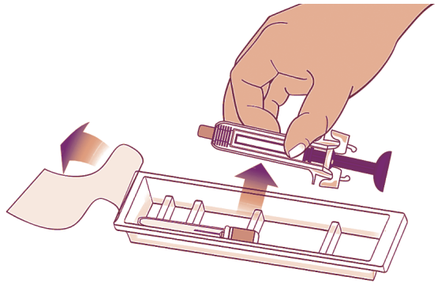

Figure F

Please see Important Safety Information including serious side effects on pages 13-15, full Prescribing Information, including Boxed WARNING, Medication Guide and Instructions for Use.

Preparing for an injection

6. Inspect the medicine and prefilled syringe (see Figure G).

Do not use the prefilled syringe if:

- The prefilled syringe has been dropped or shaken.
- Any part of the prefilled syringe appears cracked or damaged.
- The liquid is foamy, cloudy, hazy or contains particles.
- The expiration date has passed.

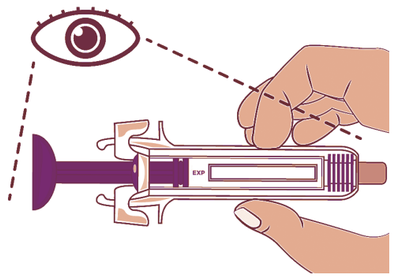

Figure G

7. Attach needle to prefilled syringe:
Grasp the prefilled syringe in the middle of the syringe body with one hand. With the other hand, hold the rubber tip cap firmly, and remove the rubber tip cap from the prefilled syringe (bend and pull) (see Figure H).

- Throw away (dispose of) the rubber tip cap in the sharps disposal container.
- **Do not** touch the activation guard.
- **Do not** push or pull on the plunger.

Figure H

Place the syringe on your work surface. Be careful that the tip of the prefilled syringe does not touch anything. If the tip of the syringe touches anything, dispose of the prefilled syringe (***see "Disposing of used prefilled syringes and needles" on page 12***) and use a new prefilled syringe and needle for the injection.

Please see Important Safety Information including serious side effects on pages 13-15, full Prescribing Information, including Boxed WARNING, Medication Guide and Instructions for Use.

8. Grasp the packaged needle firmly in both hands. Break the seal of the needle, using a twisting motion, and remove the plastic needle cap (see Figure I).

- Throw away (dispose of) the needle cap right away in the sharps disposal container.
- **Do not** remove the needle shield that protects the needle.

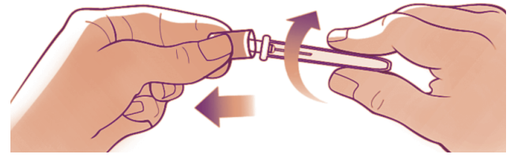

Figure I

9. Attach the needle to the prefilled syringe by pushing it firmly straight onto the prefilled syringe and by twisting or turning it slightly (see Figure J).

10. Put the prefilled syringe on its side with the needle shield on. This will keep the needle from touching anything before you use it.

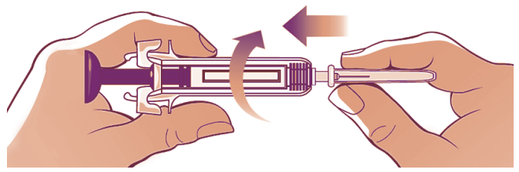

Figure J

Selecting and preparing a subcutaneous (under the skin) injection site

IMPORTANT: Follow your healthcare provider's instructions for how you should inject Mircera.

If your healthcare provider tells you to inject Mircera as a subcutaneous (under your skin) injection, give your dose as described below.

After you prepare the prefilled syringe:

1. Choose an injection site as shown in Figure K. The three sites where you can inject Mircera include:

- the outer area of the upper arms (only if someone else is giving you the injection)
- the front of the middle thighs
- the abdomen, except for the 2-inch area around the navel (belly-button)

Choose a new injection site each time you inject Mircera, at least 1-inch from the area you used for the previous injection. This helps to avoid soreness at any one site.

Do not inject Mircera into moles or into an area of your body that is tender, red, bruised, hard, or that has scars or stretch marks, or is not intact.

Do not *inject into areas that could be irritated by a belt or waistband.*

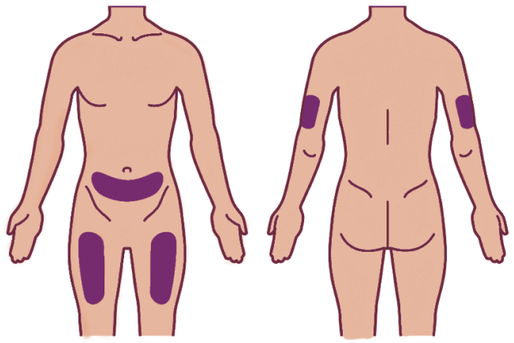

Figure K

2. Clean the injection site with an alcohol swab (see Figure L).

- Let the skin dry for about 10 seconds.
- **Do not** touch this area again before giving the injection.

Do not *fan or blow on the clean area.*

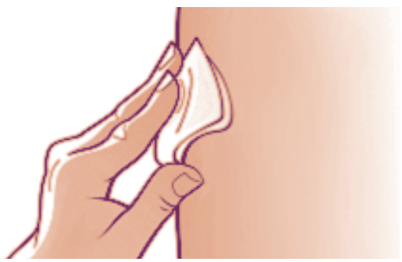

Figure L

3. Hold the prefilled syringe firmly with one hand in the middle of the syringe body and pull off the needle shield with the other hand (see Figure M). Throw away the needle shield in the sharps disposal container.

- **Do not** touch the needle or let it touch any surface.
- You may see a drop of liquid at the end of the needle. This is normal.
- **Do not** reattach the needle shield after removal.

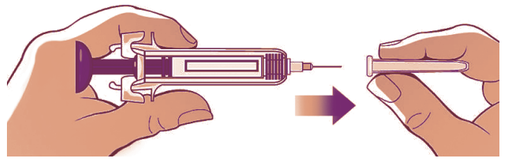

Figure M

4. Check the prefilled syringe for air bubbles. To remove air bubbles from the prefilled syringe, hold the syringe by the body with the needle pointing up. Tap the prefilled syringe body gently to bring the air bubbles to the top (see Figure N).

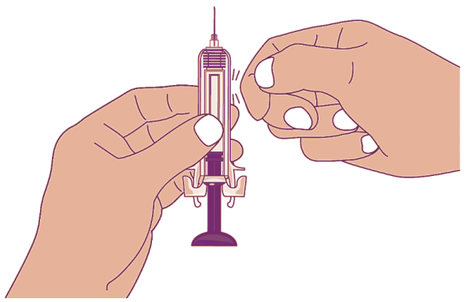

Figure N

5. Push the plunger up gently and slowly until you see a drop of liquid coming out of the needle (see Figure O).

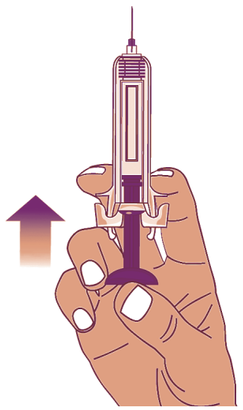

Figure O

Injecting Mircera

1. Find a comfortable position to give an injection of Mircera.

   Hold the prefilled syringe in the hand that you will use to inject Mircera. Use the other hand to pinch a fold of loose skin at the cleaned injection site (see Figure P).

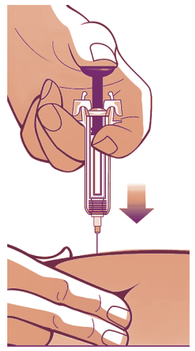

Figure P

2. Hold the prefilled syringe like a pencil. Fully and carefully insert the needle into the skin in a quick "dart-like" motion. Insert straight up and down (90 degree angle) into the skin. Keep the prefilled syringe in the skin and slowly let go of the pinch of skin.

   - **Do not** move the needle while it is inserted in the skin.

   Slowly push the plunger with your thumb all the way down while holding the prefilled syringe with your first finger and your middle finger against the finger grips until all the medicine is injected. The plunger rod should be fully pushed down (depressed) until you hear a click indicating the activation of the needle guard (see Figure Q).

   - **Do not** release the plunger before the end of injection or before the plunger is completely pushed down (depressed).
   - The plastic needle guard (a safety guard to prevent accidental needle sticks) will not move forward to cover the needle unless the full dose is given.

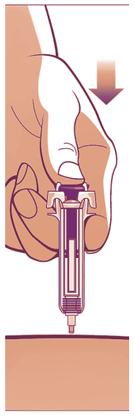

Figure Q

Please see Important Safety Information including serious side effects on pages 13-15, full Prescribing Information, including Boxed WARNING, Medication Guide and Instructions for Use.

3. Take the needle out of the skin **without** releasing the plunger (see Figure R).

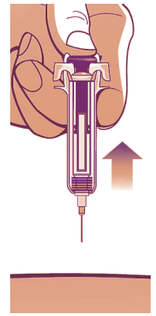

Figure R

4. Release the plunger after removing the needle from the skin. This will allow the prefilled syringe to move back until the entire needle is covered with the needle guard (see Figure S).

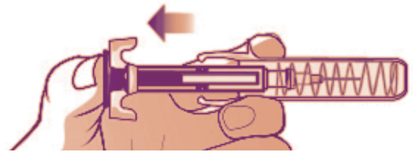

Figure S

5. Now the tear-off label can be removed, if necessary to keep a record of the dose taken (see Figure T).

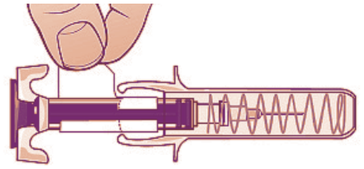

Figure T

6. **After the injection:** Place a sterile cotton ball or gauze over the injection site and press for several seconds (see Figure U).

   - **Do not** rub the injection site with an unclean hand or cloth.

   If needed, you may cover the injection site with a small adhesive bandage.

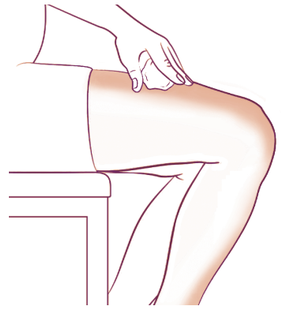

Figure U

7. **Dispose of the used prefilled syringe:**
   - Throw away (dispose of) the used prefilled syringe and the attached needle in the sharps container right away.
   - **Do not** reuse your prefilled syringe or needle.
   - See **"Disposing of used prefilled syringes and needles"** on page 12.

Disposing of used prefilled syringes and needles

- Put your used needles and prefilled syringes in an FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose needles and prefilled syringes in your household trash**.
- If you **do not** have an FDA-cleared sharps disposal container, you may use a household container that is:
  - made of heavy-duty plastic,
  - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
  - upright and stable during use,
  - leak-resistant, and
  - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles, syringes and prefilled injectors. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal
- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. **Do not** recycle your used sharps disposal container.

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

If you or your caregiver has been trained to give Mircera shots (injections) at home

- Be sure that you read, understand, and follow the "Instructions for Use" that come with Mircera.
- Take Mircera exactly as your healthcare provider tells you to. Do not change the dose of Mircera unless told to by your healthcare provider.
- Your healthcare provider will show you how much Mircera to use, how to inject it, how often it should be injected, and how to safely throw away the used prefilled syringes and needles.
- If you take more than your prescribed dose of Mircera, call your healthcare provider right away for instructions on what to do.
- During treatment with Mircera, continue to follow your healthcare provider's instructions for diet, dialysis, and medicines, including medicines for high blood pressure.
- Have your blood pressure checked as instructed by your healthcare provider.

Please see Important Safety Information including serious side effects on pages 13-15, full Prescribing Information, including Boxed WARNING, Medication Guide and Instructions for Use.

Indications

Mircera is a prescription medicine used to treat anemia. Mircera may be used to treat anemia if it is caused by chronic kidney disease (CKD). Mircera is used to reduce or avoid the need for red blood cell (RBC) transfusions.

Mircera may be used to treat CKD-related anemia in:

- adults who may or may not be on hemodialysis, **and**
- children ages 5 to 17 years on hemodialysis.

Mircera should not be used:

- in the treatment of anemia that is caused by cancer chemotherapy.
- in place of emergency treatment for anemia (RBC transfusions).

Mircera has not been proven to improve the quality of life, fatigue, or well-being.

It is not known if Mircera is safe and effective in children:

- for subcutaneous use
- below the age of 5 years
- receiving peritoneal dialysis or who are not yet treated with dialysis
- whose anemia is not already controlled with another ESA

IMPORTANT SAFETY INFORMATION

Mircera may cause serious side effects that can lead to death, including:

For people with cancer:

- Mircera should not be used to treat anemia that is caused by cancer chemotherapy. If you have certain cancers, your tumor may grow faster and you may die sooner if you take Mircera.

For all people who take Mircera:

- **Serious heart problems, such as heart attack or heart failure, and stroke**
  You may die sooner if you are treated with Mircera to increase red blood cells (RBCs) to near the same level found in healthy people.
- **Blood clots**
  Blood clots may happen at any time while taking Mircera. If you are receiving Mircera for any reason and you are going to have surgery, talk to your healthcare provider about whether or not you need to take a blood thinner to lessen the chance of blood clots during or following surgery. Blood clots can form in blood vessels (veins), especially in your leg (deep venous thrombosis or DVT). Pieces of a blood clot may travel to the lungs and block the blood circulation in the lungs (pulmonary embolus).

Please see full Prescribing Information, including Boxed WARNING, Medication Guide and Instructions for Use for Mircera (methoxy polyethylene glycol-epoetin beta) Injection, for Intravenous or Subcutaneous Use.

IMPORTANT SAFETY INFORMATION cont'd

Call your healthcare provider or get medical help right away if you have any of these symptoms:

- Chest pain
- Trouble breathing or shortness of breath
- Pain in your legs, with or without swelling
- A cool or pale arm or leg
- Sudden confusion, trouble speaking, or trouble understanding others' speech
- Sudden numbness or weakness in your face, arm or leg, especially on one side of your body
- Sudden trouble seeing
- Sudden trouble walking, dizziness, loss of balance or coordination
- Loss of consciousness (fainting)
- Hemodialysis vascular access stops working

Mircera should not be used if you:

- have high blood pressure that is not controlled (uncontrolled hypertension).
- have been told by your healthcare provider that you have or have ever had a type of anemia called Pure Red Cell Aplasia (PRCA) that starts after treatment with Mircera or other erythropoietin protein medicines.
- have had serious allergic reactions to Mircera.

Before you start Mircera, please tell your healthcare provider about all of your medical conditions, including **if you:**

- have heart disease.
- have or develop cancer.
- have high blood pressure.
- have had a seizure (convulsion) or stroke.
- receive dialysis treatment.
- are pregnant or plan to become pregnant. It is not known if Mircera may harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Mircera passes into your breast milk.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Tell your healthcare provider if you have used Mircera in the past and had an allergic reaction.

If you are recommended for treatment with Mircera, your healthcare provider should prescribe the smallest dose of Mircera that is necessary to reduce your chance of needing RBC transfusions.

Please see full Prescribing Information, including Boxed WARNING, Medication Guide and Instructions for Use for Mircera (methoxy polyethylene glycol-epoetin beta) Injection, for Intravenous or Subcutaneous Use.

If your hemoglobin level stays too high or if your hemoglobin goes up too quickly, this may lead to serious health problems which may result in death. These serious health problems may happen if you take Mircera, even if you do not have an increase in your hemoglobin level.

Mircera may cause serious side effects including:

- **High blood pressure**
  High blood pressure is a common side effect of Mircera in patients with chronic kidney disease. Your blood pressure may go up or be difficult to control with blood pressure medicine while taking Mircera. This can happen even if you have never had high blood pressure before. If your blood pressure does go up, your healthcare provider may prescribe new or more blood pressure medicine. Your healthcare provider should check your blood pressure often.
- **Seizures**
  If you have any seizures while taking Mircera, get medical help right away and tell your healthcare provider.
- **No response or loss of your hemoglobin response to Mircera**
  If your hemoglobin does not increase, or if the increase cannot be maintained, your healthcare provider will look for the cause of the problem. Your dose of Mircera or other medicines may need to be changed.
- **Antibodies to Mircera**
  Your body may produce antibodies to Mircera. These antibodies can block or lessen your body's ability to make red blood cells, and cause you to have severe anemia. Call your healthcare provider if you have unusual tiredness, lack of energy, dizziness or fainting. You may need to stop taking Mircera.
- **Serious allergic reaction**
  Serious allergic reactions can cause itching, shortness of breath, wheezing, dizziness and fainting because of a drop in blood pressure, swelling around your mouth or eyes, fast pulse, or sweating. If you have a serious allergic reaction, stop using Mircera and call your healthcare provider or get emergency medical help right away.
- **Severe skin rash**
  Severe skin rash can occur. If you develop a new rash, call your healthcare provider right away.

Common side effects of Mircera include:

- Diarrhea
- Pain or swelling (inflammation) in your nose or throat (nasopharyngitis).

These are not all of the possible side effects of Mircera. Your healthcare provider can give you a more complete list. Tell your healthcare provider about any side effects that bother you or that do not go away.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

MIRCERA®
methoxy polyethylene glycol-epoetin beta

Please see Important Safety Information including serious side effects on pages 13-15, full Prescribing Information, including Boxed WARNING, Medication Guide and Instructions for Use.

CSL Vifor

HQ-MIR-1900023 04/23