

USING THE  
**ARANESP® SINGLEJECT®**  
**PREFILLED SYRINGE**

**A guide for patients**

**P Aranesp®**  
darbepoetin alfa injection





You have received this booklet because your doctor has decided that using Aranesp<sup>®</sup> at home is right for you. This booklet is designed to clearly explain how to properly use your prescribed dose of Aranesp<sup>®</sup> using the SingleJect<sup>®</sup> prefilled syringe. Refer to these instructions every time you inject Aranesp<sup>®</sup>. Always call your doctor, nurse or pharmacist if you do not understand any of the instructions.

## What is anemia?

Anemia is a condition where your blood does not contain enough red blood cells. Red blood cells are responsible for carrying oxygen to your organs and body tissues. If the number of red blood cells in your blood is decreased, the amount of oxygen delivered throughout your body is also decreased. This may cause several symptoms that are typical of anemia including fatigue, weakness and shortness of breath. In patients with kidney failure, the kidneys do not produce enough of the natural hormone erythropoietin, which encourages your bone marrow to produce more red blood cells.

## What is Aranesp® used for?

Aranesp® is used to treat anemia associated with chronic kidney disease (kidney failure), including patients on dialysis and patients not on dialysis.

# IMPORTANT INFORMATION

Before you use an Aranesp® prefilled syringe, read the information in this brochure, including the safety information on pages 14-15.

## Storing your prefilled syringe

- Keep the prefilled syringe out of the reach of children.
- Keep the prefilled syringe in the original carton to protect from light or physical damage.
- The prefilled syringe should be kept in the refrigerator at 2°C to 8°C (36°F to 46°F).
- Do NOT store the prefilled syringe in extreme heat or cold. For example, avoid storing in your vehicle's glove box or trunk.
- Do NOT freeze.



## Using your prefilled syringe

It is important that you do not try to give the injection unless you or your caregiver have received training from your healthcare professional.

- Make sure the name Aranesp® appears on the carton and prefilled syringe label.
- Check the carton and prefilled syringe label to make sure the dose strength (number of micrograms [mcg]) matches your prescription.
- Do NOT use a prefilled syringe after the expiration date on the label.
- Do NOT shake the prefilled syringe.
- Do NOT remove the grey needle cap from the prefilled syringe until you are ready to inject.
- Do NOT use the prefilled syringe if the carton is open or damaged.
- Do NOT use a prefilled syringe if it has been dropped on a hard surface. Part of the prefilled syringe may be broken even if you cannot see the break. Use a new prefilled syringe.
- Do NOT slide the yellow safety guard over the needle before the injection. This will “activate” or lock the yellow safety guard. Use a new prefilled syringe that has not been activated and is ready to use.

In any of the above cases, use a new prefilled syringe.

- This product contains dry natural rubber, which is made from latex, within the grey needle cap. Tell your healthcare professional if you are allergic to latex.

Call your healthcare professional or Amgen Medical Information at 1-866-502-6436 if you have any questions. For more information, contact the AIDe Patient Support Program (by Amgen Entrust®)\* at 1-866-479-6377.

\* Amgen Entrust is our unified patient support program platform, built on the legacy of our branded support programs.

# STEP 1: PREPARE



Remove the prefilled syringe carton from the refrigerator.

Remove one prefilled syringe from the carton and put the original package with any unused prefilled syringes back in the refrigerator.

- Do NOT use the prefilled syringe if the carton is damaged.
- Do NOT try to warm the prefilled syringe by using a heat source such as hot water or microwave.
- Do NOT leave the prefilled syringe in direct sunlight.
- Do NOT shake the prefilled syringe.

Open the tray by peeling away the cover. Grab the yellow safety guard to remove the prefilled syringe from the tray.

For safety reasons:

- Do NOT grab the plunger rod.
- Do NOT grab the grey needle cap.





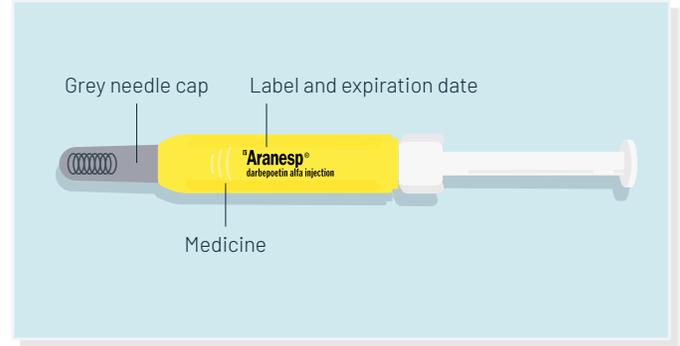
Inspect the medicine and prefilled syringe.

Always hold the syringe by the syringe barrel.

Make sure the medicine in the prefilled syringe is clear and colourless.

Do NOT use the prefilled syringe if:

- the medicine is cloudy or discoloured or contains flakes or particles.
- any part appears cracked or broken.
- the prefilled syringe has been dropped.
- the grey needle cap is missing or not securely attached.
- the expiration date printed on the label has passed.



Gather all materials needed for your injection.

Wash your hands thoroughly with soap and water.

On a clean, well-lit work surface, place the:

- Prefilled syringe
- Alcohol wipe
- Cotton ball or gauze pad
- Adhesive bandage
- Sharps disposal container



# STEP 2: GET READY



Prepare and clean site for subcutaneous injection.

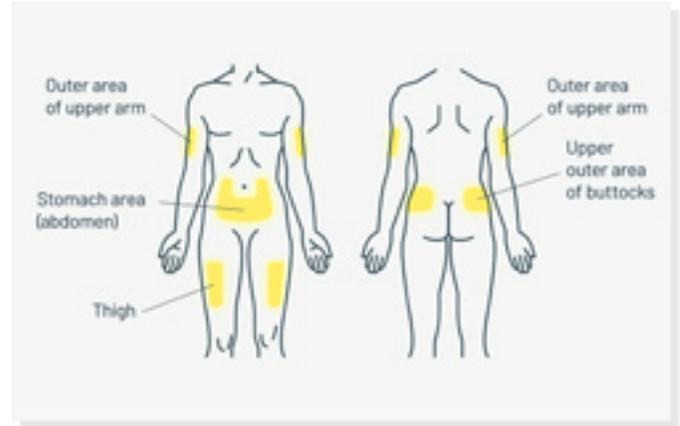
You can use:

- Thigh
- Stomach area (abdomen), except for a 5 cm (2-inch) area right around your navel (belly button).
- Upper outer area of your buttocks (only if someone else is giving you the injection).
- Outer area of upper arm (only if someone else is giving you the injection).

Clean the injection site with an alcohol wipe. Let your skin dry.

- Do NOT touch this area again before injecting.
- Choose a different site each time you give yourself an injection. If you want to use the same injection site, make sure it is not the same spot on the injection site area you used for a previous injection.
- Do NOT inject into areas where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.

**Important:** Follow your healthcare professional's instructions about selecting sites for injection appropriate to you and about changing the site for each injection.

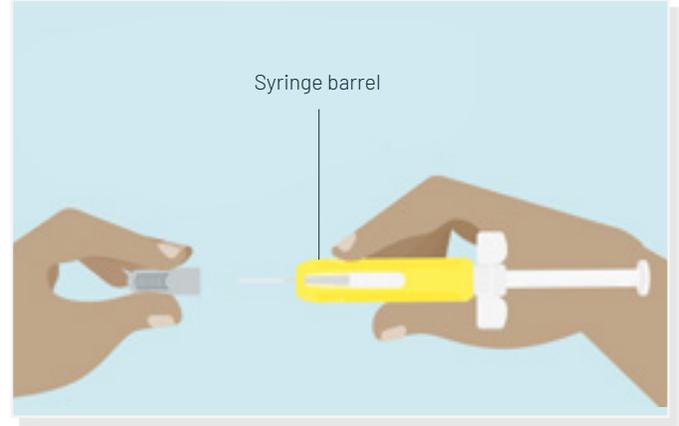




Hold the prefilled syringe by the syringe barrel. Carefully pull the grey needle cap straight off and away from your body.

- Do NOT remove the grey needle cap from the prefilled syringe until you are ready to inject.
- Do NOT twist or bend the grey needle cap.
- Do NOT hold the prefilled syringe by the plunger rod.
- Do NOT put the grey needle cap back onto the prefilled syringe.

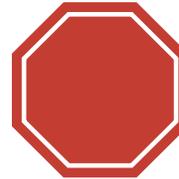
**Important:** Throw the grey needle cap into the sharps disposal container.



## Read this before you inject.

In Step 3, choose between Subcutaneous (3a) OR Port injection (3b) based on your healthcare professional's instructions.

**When you feel you are ready, please continue.**



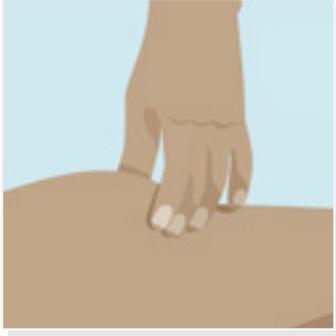
# STEP 3: INJECTION

Choose between subcutaneous (3a) OR port injection (3b) based on your healthcare professional's instructions.

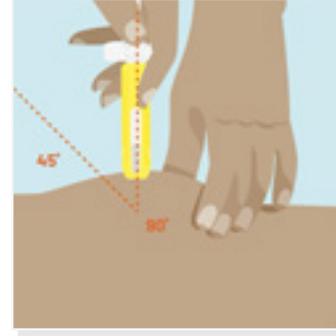
## Step 3a: Subcutaneous (under the skin) injection



Pinch your injection site to create a firm surface.  
**Important:** Keep skin pinched while injecting.



Hold the pinch. Insert the needle into the skin at 45 to 90 degrees.



Continue to hold the pinch. Using slow and constant pressure, push the plunger rod until it reaches the bottom.

When done, gently pull the syringe off of your skin and continue to Step 4.

**Important:** When you remove the syringe, if it looks like the medicine is still in the syringe barrel, this means you have not received a full dose. Call your healthcare professional immediately.



## Step 3b: Port injection

**If your healthcare professional has prescribed an injection into your home hemodialysis system, you should be first trained by your healthcare professional and then follow the procedure described below.**

- A.** Locate the port on the hemodialysis tubing where your healthcare professional prescribed you to inject. Do NOT inject into the hemodialysis tubing.
- B.** Clean the port with an alcohol wipe.
- C.** Insert the prefilled syringe needle at a 90° angle, directly into the centre of the rubber septum located on the cleaned port. Do NOT bend the needle. The rubber septum may require increased pressure to penetrate with the needle.
- D.** Push the plunger down until it reaches the bottom.
- E.** Remove the syringe from the port.

**Now, continue to Step 4: Finish**

# STEP 4: FINISH



Before you finish!



For your safety, pull the yellow safety guard until it clicks and covers the needle.

Once extended, the yellow safety guard will lock into position and will not slide back over the needle.

Keep your hands away from the needle at all times.



Discard (throw away) the used prefilled syringe.

- Put the used prefilled syringe in a sharps disposal container right away after use. Do NOT throw away (dispose of) the syringe in the household trash.
- If you do not have a sharps disposal container, you may use a household container that:
  - is made of a heavy-duty plastic,
  - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
  - is upright and stable during use,



- is leak-resistant, and
- is properly labelled 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 provincial or local laws about how you should throw away used needles and syringes.
- Do NOT reuse the prefilled syringe.
- Do NOT recycle the prefilled syringe or sharps disposal container or throw them into household trash.

**Important:** Always keep the sharps disposal container out of the reach of children.



Examine the subcutaneous injection site.

If there is blood, press a cotton ball or gauze pad on the injection site. Do NOT rub the injection site. Apply an adhesive bandage if needed.

## Serious Warnings and Precautions

### All Patients

- To minimize the risks for death and serious cardiovascular (heart and blood vessel-related) side effects and stroke, your doctor will prescribe the recommended dosage for each indication.
- Patients with uncontrolled high blood pressure should not be treated with Aranesp®; blood pressure should be adequately controlled before receiving Aranesp®.
- Aranesp® should be used with caution in patients with a history of seizures.
- Antibody-mediated Pure Red Cell Aplasia (PRCA) has been reported after months to years of treatment with erythropoiesis-stimulating agents (ESAs). If you develop PRCA, you may suddenly become severely anemic and this could result in a dependency on blood transfusions.

### Chronic Kidney Disease 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 will try to keep your hemoglobin between 100 and 115 g/L, not to exceed 120 g/L.

### Do not use Aranesp® if:

- You have uncontrolled high blood pressure.
- Your body makes antibodies (develop Pure Red Cell Aplasia) following treatment with any erythropoiesis-stimulating agent (ESA).
- You are allergic to Aranesp® or any of the ingredients (for example, polysorbate 80) in Aranesp®.
- You are allergic to other erythropoietins, or medicines made using mammalian cells.

Talk to your doctor if you have any questions about this information.

### To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Aranesp®. Talk about any health conditions or problems you may have, including if you:

- Have a hemodialysis vascular access, continue to check the access to make sure it is working. Call your doctor or dialysis centre right away if you have any problems or questions. Always call your doctor if you do not feel well while using Aranesp®.

### **Other warnings you should know about:**

Please tell your doctor if you are suffering or have suffered from:

- High blood pressure
- Heart disease (e.g. angina)
- Epileptic fits (seizures)

It is important to tell your doctor if you:

- Are pregnant
- Think you may be pregnant
- Plan to get pregnant, or are breast-feeding

Too much Aranesp® may cause your body to produce too many red blood cells too fast (lead to a hemoglobin that is too high). Producing too many red blood cells, or producing them too fast, may cause serious problems. It is important that your blood pressure be monitored often and to report any changes outside of the guidelines that your doctor has given you, especially if you have heart disease. Certain laboratory tests, such as hemoglobin, hematocrit, or iron level measurements, may also need to be done more often and be reported to your doctor or dialysis centre.

It is important to keep all appointments for blood tests to allow your doctor to adjust the dosage of Aranesp® as needed.

Over time, many patients also need to take iron. Your doctor will know when or if you need an iron supplement from your laboratory test results. Do not change the dose of Aranesp®.

Be sure to change the site for each injection to avoid soreness at any one site. Occasionally a problem may develop at the injection site. If there is a lump, swelling, or bruising at the injection site that does not go away, talk to your doctor.

Pure Red Cell Aplasia (PRCA), in association with antibodies, has been observed in patients treated with ESAs. PRCA is a condition in which severe and sudden anemia (characterized by symptoms such as severe tiredness/fatigue, and shortness of breath on mild exertion) develops due to failure of the bone marrow to produce red blood cells. PRCA could result in a dependency on blood transfusions. Should you be diagnosed with PRCA, your doctor will stop your Aranesp® therapy and may initiate treatment with blood transfusions to help increase your red blood cell count. PRCA has been reported predominantly in patients with chronic kidney disease. PRCA has been reported in a very rare number of patients exposed to Aranesp® subcutaneously (under your skin).

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

### **The following may interact with Aranesp®:**

No drug-drug interaction studies for Aranesp® have been carried out with other medications commonly used to treat chronic kidney disease or cancer.

These are not all the possible side effects you may have when taking Aranesp®. If you experience any side effects not listed here, tell your healthcare professional.



# ARANESP<sup>®</sup> INJECTION GUIDE

## AT YOUR FINGERTIPS

Access **step-by-step video guides** to support your at home injection of Aranesp<sup>®</sup>.

### What You'll Learn:

- How to prepare your Aranesp<sup>®</sup> prefilled syringe
- Step by step instructions for subcutaneous or port injection\*
- Helpful tips for using and storing your Aranesp<sup>®</sup> prefilled syringe

### HOW TO GET STARTED:

1. **Scan the QR Code**  
to access the content.
2. **Enter the DIN<sup>†</sup> 02392321**  
to unlock and watch the videos.



\* Aranesp is administered as an injection. Based on your healthcare professional's instructions, one of the following methods will be used: under your skin (subcutaneous) or into the port of the venous line that connects the hemodialysis machine to your vein (intravenous), if you are on hemodialysis at home.

† A DIN (Drug Identification Number) is an eight-digit number that uniquely identifies a drug in Canada. You can find the DIN for Aranesp<sup>®</sup> on its packaging or ask your pharmacist or healthcare provider for assistance. Note that the DIN provided here may not be the same as the one on your Aranesp<sup>®</sup> packaging.

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