

FDA COMPLETE RESPONSE AND SAFETY LABELING CHANGE ORDER: JULY 30, 2008

Patient Instructions for Use

**Aranesp[®] (Air-uh-nesp)
(darbepoetin alfa)**

Single-Use Prefilled SureClick[™] Autoinjector

Use these instructions if you or your caregiver has been trained to give Aranesp injections at home. Do not give yourself the injection unless you have received training from your healthcare provider. If you are not sure about giving the injection or if you have questions, ask your healthcare provider for help.

Before reading these instructions for use, read the Medication Guide that comes with Aranesp for the most important information you need to know.

How should I take Aranesp?

This section explains how to give yourself an injection of Aranesp using the single-use prefilled SureClick[™] autoinjector. You will give the injection into the tissue just under your skin. This is called a subcutaneous injection.

To give yourself a subcutaneous injection, you need:

- A new, single-use Aranesp prefilled SureClick[™] autoinjector
- Alcohol or sterile wipe
- A puncture-proof container so you can safely throw away the used autoinjector

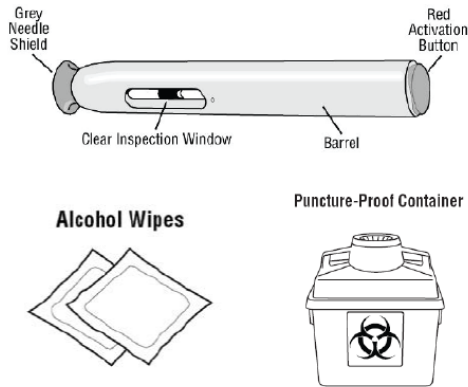


Figure 1

Important: Follow these instructions exactly to help avoid infections.

1. Take your autoinjector out of the refrigerator. Keep the autoinjector in the box until you are ready to use it.
 - **Do not shake your autoinjector.** Shaking could cause Aranesp not to work. If you shake your Aranesp prefilled SureClick[™] autoinjector, the solution may look foamy and it should not be used.
 - **Do not freeze your autoinjector. Do not use an autoinjector that has been frozen.**
 - Do not leave your autoinjector in bright light. Do not use an autoinjector that has been left in light.

2. Check that your single-use Aranesp prefilled SureClick™ autoinjector is the correct dose that your healthcare provider has prescribed.
3. Do not use your autoinjector after the expiration date on the carton and on the autoinjector label.
4. Remove the autoinjector from the box. During this time, protect the solution from light.
5. **Do not** warm your single-use Aranesp prefilled SureClick™ autoinjector (for example, do not warm it in a microwave or in hot water).
6. **Do not** remove the grey needle shield from the autoinjector until you are ready to inject.
7. **Do not** put the grey needle shield back into the autoinjector.
8. Look at Aranesp through the inspection window. It should be clear and colorless. **Do not inject Aranesp if it looks discolored, cloudy, or has lumps, flakes, or particles.**
9. Wash your hands well.
10. Find a comfortable, well-lit place and put your supplies (autoinjector, alcohol or sterile wipe, and puncture-proof container) where you can reach them.

On what part of my body should I give my injection?

Inject your single-use Aranesp prefilled SureClick™ autoinjector into:

- The front center of your thighs
- The back of your upper arms, only if someone else is injecting you

The abdomen may be used if your healthcare provider tells you it is alright.

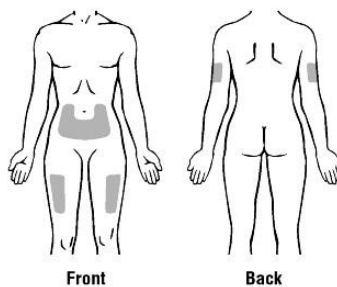


Figure 2

Change the site for each injection to avoid soreness at any one site.

- Do not inject into areas where the skin is tender, bruised, red, or hard.
- Avoid areas with scars or stretch marks.

Sometimes 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 healthcare provider.

How do I give an injection into my thigh or the back of my arm?

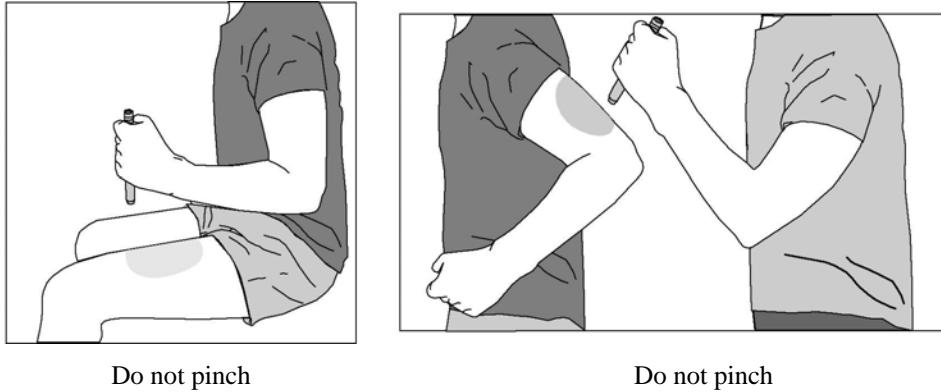


Figure 3

1. Wipe the injection site with a new alcohol or sterile wipe and allow your skin to dry. **Do not touch this area again before giving the injection.**
2. Pick up your single-use Aranesp prefilled SureClick™ autoinjector in one hand and remove the grey needle shield by pulling it straight off. Do not twist it off and do not recap the grey needle shield, as either of these may damage the needle inside the autoinjector. Your single-use Aranesp prefilled SureClick™ autoinjector has a cover that will protect you from needlesticks or an accidental loss of medicine by bumping or touching. See Figure 4.

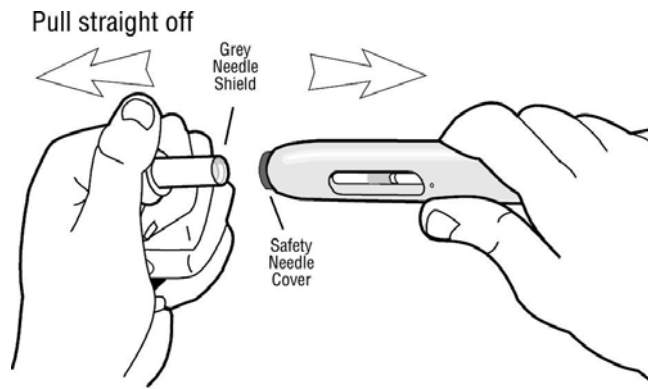


Figure 4

3. **Without** pressing the red activation button, place the open end of the autoinjector on the injection site straight up and down at a right angle (90°) to your skin. Push the safety needle cover firmly against your skin to unlock it. **Keep holding the autoinjector firmly against your skin.** See Figure 5.

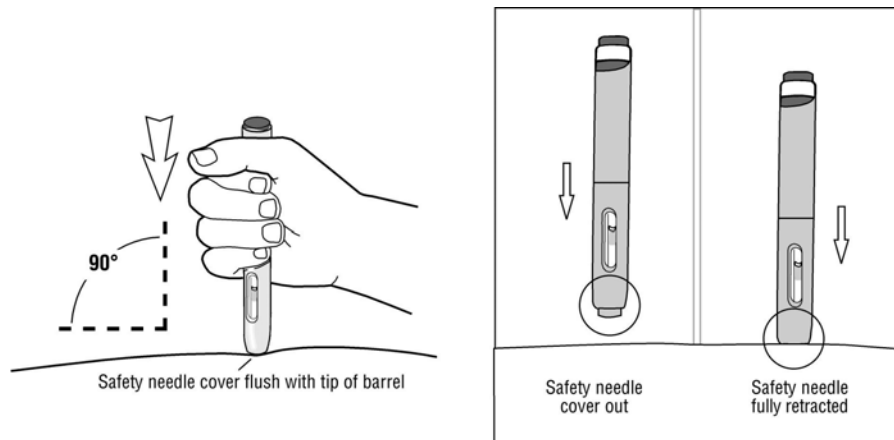


Figure 5

- To start the injection: (1) press the red button; you will hear the first click, and then (2) right away, release your thumb. This starts the injection. **Do not lift** the autoinjector off of your skin. See Figure 6.

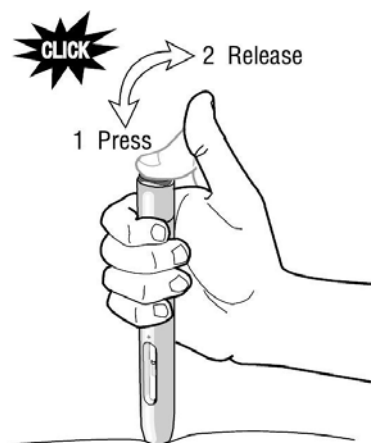


Figure 6

- Wait until you hear the second click.** After you hear the second click, lift the autoinjector straight up from the injection site. Your injection is finished. The safety needle cover on the autoinjector will automatically extend to cover the needle.

If you did not remove your thumb from the red button, you will not hear the second “click.” If this happens, slowly count to 15 before lifting the autoinjector from the injection site. See Figure 7.

Call your healthcare provider or 1-866-55AMGEN if you have trouble starting (activating) the autoinjector or cannot push in the red button to administer the medicine.

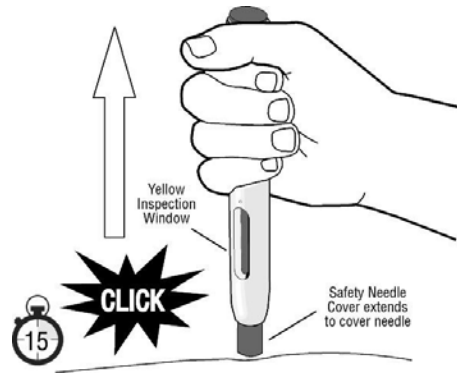


Figure 7

The needle safety cover will move down over the needle and lock into place. The inspection window will be yellow, confirming the injection is finished. Make sure that the inspection window is yellow before lifting the autoinjector. This tells you that the injection is finished. You do not need to replace the grey needle shield. See Figure 8.

If the inspection window is not yellow, do not try to use the autoinjector again.

If you think that you have not received the full dose of Aranesp, do not repeat the injection using a new autoinjector.

Call your healthcare provider or 1-866-55AMGEN for assistance.

If you notice a spot of blood at the injection site, dab away with a cotton ball or tissues. Do not rub the injection site. If needed, you may cover the injection site with a bandage.

How do I inject into the abdomen?

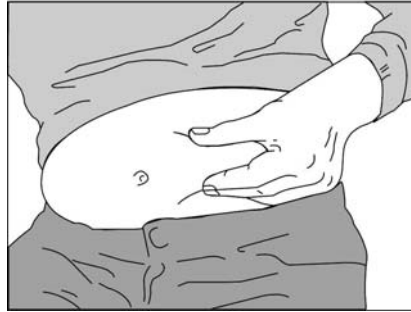


Figure 9

Important skin pinch technique

When you use the skin pinch technique it is important to create a firm site for the injection.

- Choose a site at least 2 inches away from the belly button (navel).
- Pinch the skin of the abdomen **firmly** between the thumb and fingers. Create a space at least 2 inches wide (twice the width of the tip of the autoinjector). Keep a firm skin pinch for the whole injection. See Figure 10.



Pinch
Figure 10

- Follow steps 1-5 above.

Remember

If you have any problems, ask your healthcare provider for help and advice.

How should I dispose of used autoinjectors?

Do not reuse the Aranesp prefilled SureClick™ autoinjector. **Do not** put the grey needle shield back into the autoinjector.

Throw away the used autoinjector as instructed by your healthcare provider or by following these steps:

- Do not throw the used autoinjector in the household trash or recycle.
- Place the used autoinjector in a puncture-proof disposable container with a lid. Do not use glass or clear plastic containers, or any container that will be recycled or returned to a store.
- Keep the container out of the reach of children.
- When the container is full, tape around the cap or lid to make sure the cap or lid does not come off. Throw away the puncture-proof disposable container as instructed by your healthcare provider. There may be special state and local laws for disposing of used needles and syringes. **Do not throw the disposable container in the household trash. Do not recycle.**

Keep Aranesp out of reach of children.

AMGEN®

Manufactured by:

Amgen Manufacturing, Limited, a subsidiary of Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

© 2001-2008 Amgen Inc. All rights reserved.

3xxxxxx - v
Revised: