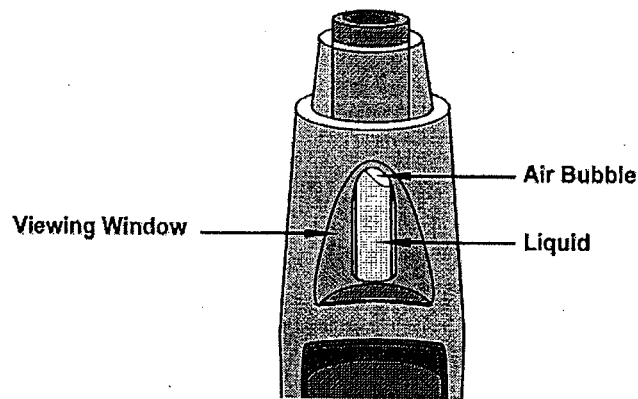


1.4 Check the Liquid in the SmartJect autoinjector

- Look through the viewing window of the SmartJect autoinjector. See Figure 3. Make sure that the liquid in the prefilled syringe is clear and colorless to slightly yellow in color. You may see a small amount of tiny particles that are white, or that you can see through. Do not inject the liquid if it is cloudy or discolored, or has large particles in it.
- You may also notice an air bubble. This is normal. See Figure 3.

Figure 3

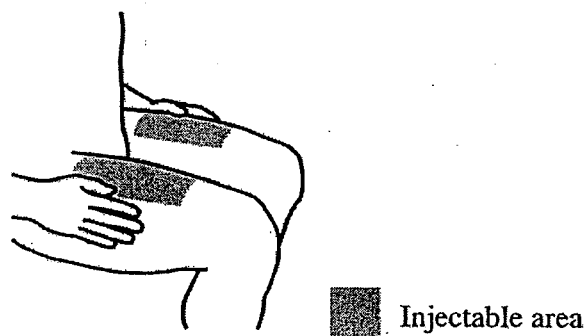


Step 2: Choose and prepare the injection site

2.1 Choose the Injection Site

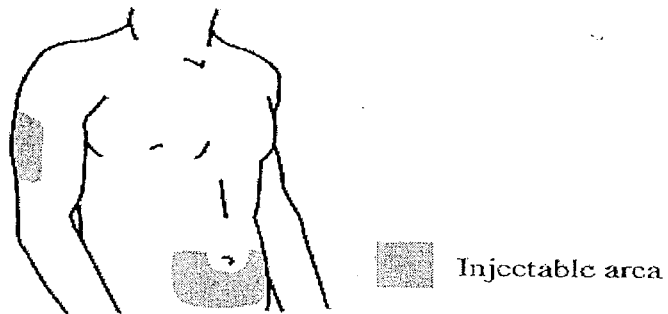
- The recommended injection site is the front of your middle thighs. See Figure 4.

Figure 4



- You can also use the lower part of the abdomen below the navel (belly button), except for the two-inch area directly around the navel. See Figure 5.
- If a caregiver is giving you the injection, the outer area of the upper arms may also be used. See Figure 5.

Figure 5



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

2.2 Prepare the Injection Site

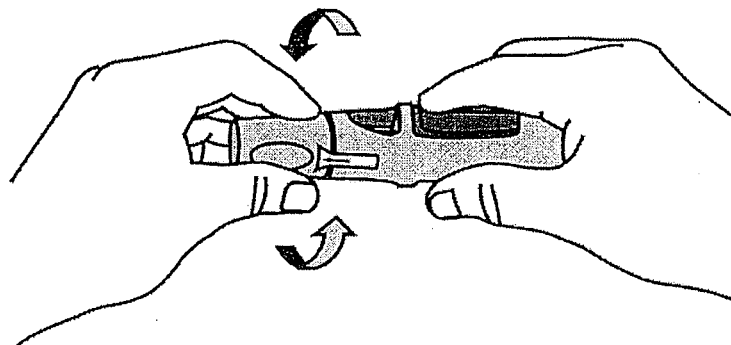
- Wash your hands well with soap and warm water.
- Wipe the injection site with an alcohol swab.
- **Do not** touch this area again before giving the injection. Allow the skin to dry before injecting.
- **Do not** fan or blow on the clean area.

Step 3: Injecting SIMPONI using the single dose SmartJect autoinjector

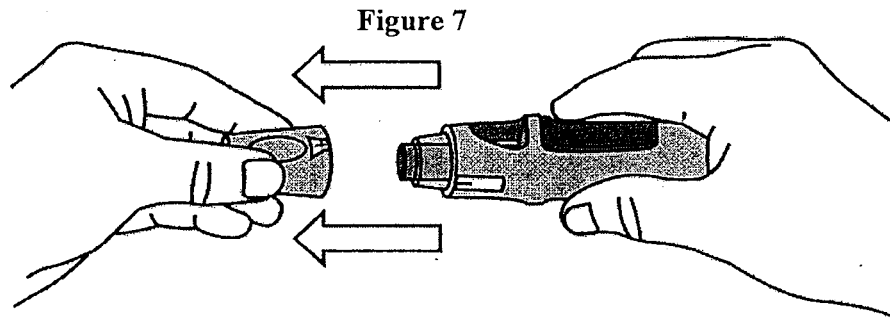
3.1 Remove the Cap

- Do not remove the cap until you are ready to inject SIMPONI. Inject SIMPONI within 5 minutes after the cap has been removed.
- When you are ready to inject, twist the cap slightly to break the security seal. See Figure 6.

Figure 6



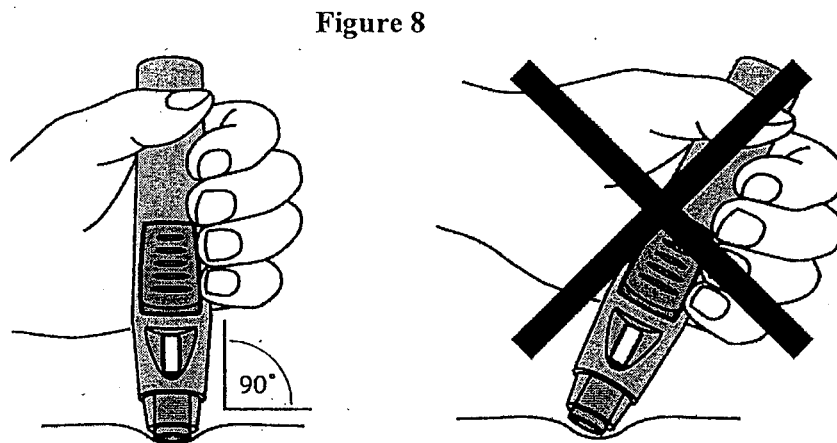
- Pull the cap off and throw it in the trash right away. See Figure 7.



- Do not put the cap back on because it may damage the needle inside the SmartJect autoinjector.
- Do not use your SmartJect autoinjector if it is dropped without the cap in place.

3.2 Push the SmartJect autoinjector against the skin

- Hold the SmartJect autoinjector comfortably in your hand.
- Do not press the button. Push the open end of the SmartJect autoinjector firmly against the skin at **90-degree angle**. See Figure 8.



- Use your free hand to pinch and hold the skin at the injection site. This may make injecting easier.

3.3 Press button to inject

- Continue to hold the SmartJect autoinjector firmly against the skin, and press the button with your fingers (see Figure 9) or thumb (see Figure 10). You will not be able to push in the button unless the SmartJect autoinjector is pushed firmly against your skin.

Figure 9

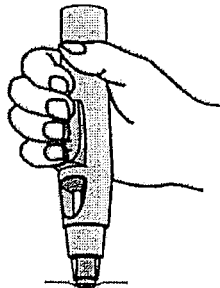
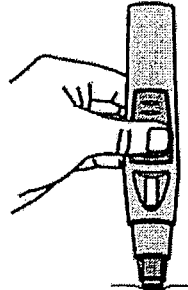
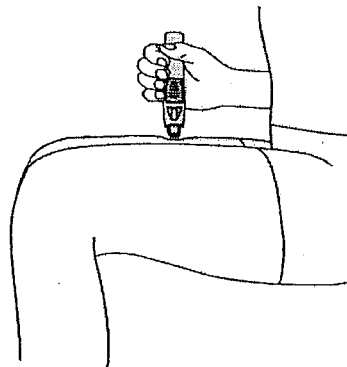


Figure 10



- After the button is pressed, it will stay pressed in so you do not need to keep pressure on it. See Figure 11.

Figure 11

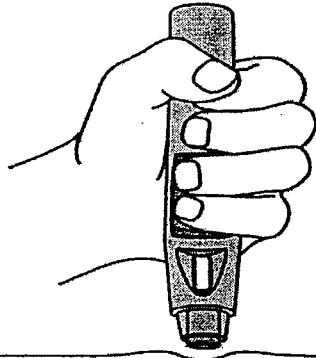


- You will hear a loud 'click' sound. This means that the injection has started. Do not pull the SmartJect autoinjector away from your skin. If you pull the SmartJect autoinjector away from the skin, you may not get your full dose of medicine. See Figure 12.
- Do not lift the SmartJect autoinjector yet.

3.4 Wait for Second "Click"

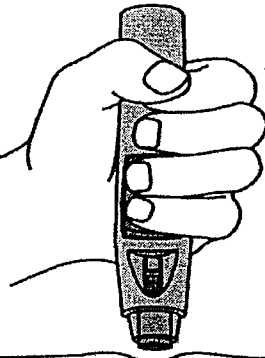
- Keep holding the SmartJect autoinjector against your skin until you hear the second 'click' sound. It usually takes about 3 to 6 seconds, but may take up to 15 seconds for you to hear the second 'click' sound. See Figure 13.
- The second 'click' sound means that the injection is finished and the needle has pulled back (retracted) into the SmartJect autoinjector.
- Lift the SmartJect autoinjector from the injection site. See Figure 14.
- If you have hearing problems, count for 15 seconds from the time you pressed the button and then lift the SmartJect autoinjector from the injection site.

Figure 12



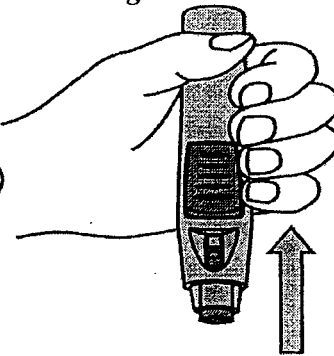
**Press Button
For 1st Click**

Figure 13



**Wait
For 2nd Click**

Figure 14



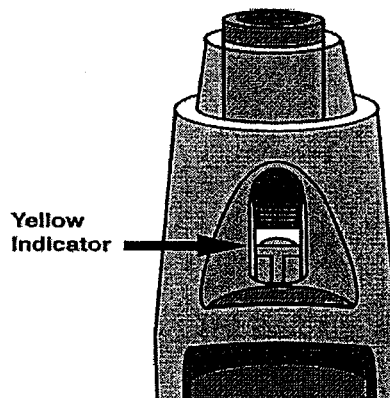
Lift

Step 4: After the injection

4.1 Check the Viewing Window

- After you finish injecting, check the viewing window to see the yellow indicator. See Figure 15. This means the SmartJect autoinjector has worked the right way.

Figure 15

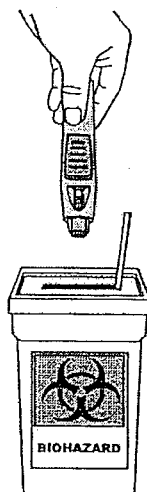


- If you do not see the yellow indicator in the viewing window, call 1-800-457-6399 for help.

4.2 Dispose of the used SmartJect autoinjector

- Place the used SmartJect autoinjector into a closable puncture-resistant container. You may use a sharps container (such as a red biohazard container), a hard plastic container (such as a detergent bottle), or a metal container (such as an empty coffee can). See Figure 16.

Figure 16



- Ask your doctor for instructions on the right way to throw away (dispose of) the container. There may be local or state laws about how you should throw away used needles and syringes.
- Do not throw away your used SmartJect autoinjector in household trash. Do not recycle.

4.3 Use Cotton Ball or Gauze

- There may be a small amount of blood or liquid at the injection site, which is normal.
- You can press a cotton ball or gauze over the injection site for 10 seconds. Do not rub the injection site.
- You may cover the injection site with a small adhesive bandage, if needed.

**Patient Instructions for Use
SIMPONI™
Prefilled Syringe**

If your doctor decides that you or a caregiver may be able to give your injections of SIMPONI at home, you should receive training on the right way to prepare and inject SIMPONI. **Do not** try to inject SIMPONI yourself until you have been shown the right way to give the injections by your doctor or nurse.

It is important to read, understand, and follow these instructions so that you inject SIMPONI the right way. Call your doctor if you or your caregiver has any questions about the right way to inject SIMPONI.

Important information about your prefilled syringe:

- Always hold the prefilled syringe by the body of the syringe.

Do not:

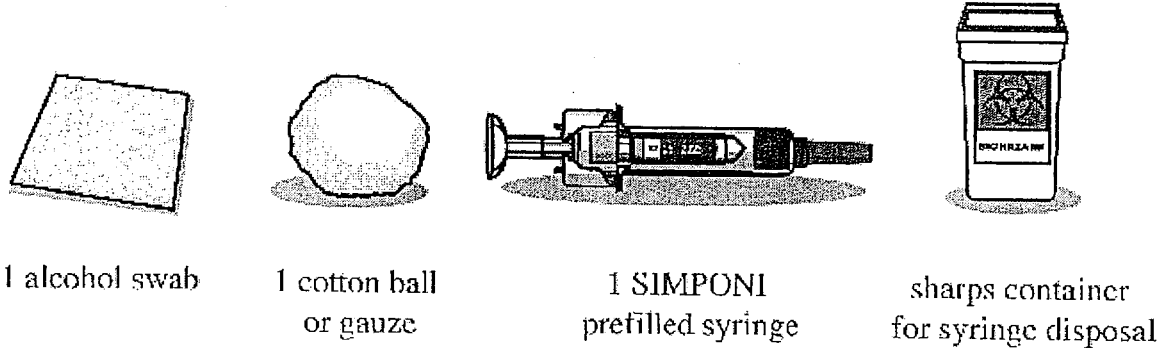
- pull back on the plunger at any time.
- shake the SIMPONI prefilled syringe. This may damage the medicine.
- remove the needle cover from the prefilled syringe until you get to that step.
- touch the needle guard activation clips to prevent covering the needle with the needle guard too soon (See Figure 2).
- use SIMPONI if it has been frozen or if it has been kept at a room temperature that is too warm. See the Medication Guide section: “How should I store SIMPONI?”
- use your SIMPONI prefilled syringe if it looks damaged.

Step 1: Gather the supplies for your injection

You will need these supplies for an injection of SIMPONI. See Figure 1.

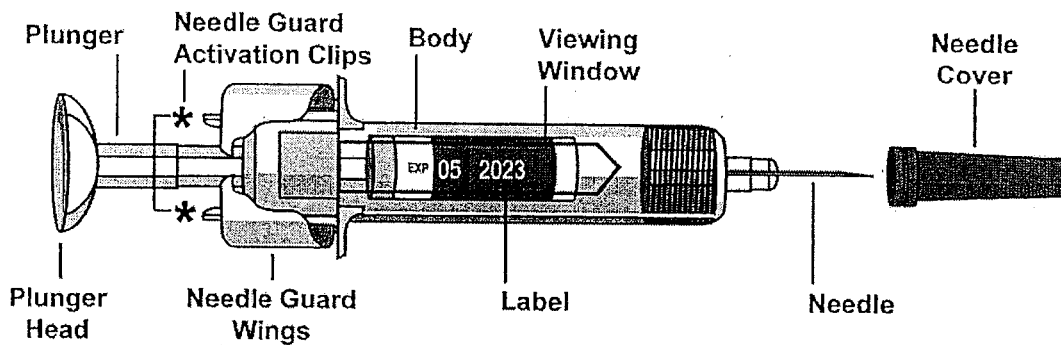
- 1 alcohol swab
- 1 cotton ball or gauze
- 1 SIMPONI prefilled syringe
- sharps container for syringe disposal

Figure 1



The diagram below shows what the prefilled syringe looks like. See Figure 2.

Figure 2



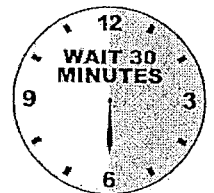
Step 2: Get ready to use your prefilled syringe

2.1 Check the Expiration Date

- Look for the expiration date printed on the back panel of the SIMPONI carton.
- **If the expiration date has passed, do not use the prefilled syringe. Call your doctor or pharmacist or call 1-800-457-6399 for help.**

2.2 Wait 30 minutes

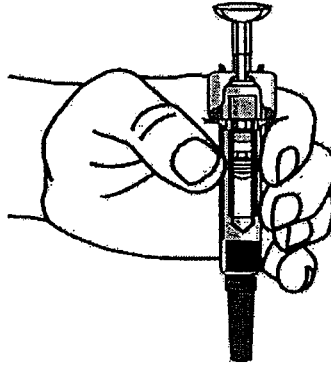
- To ensure proper injection, allow the prefilled syringe to sit at room temperature outside of the carton for 30 minutes and out of the reach of children.
- **Do not** warm the prefilled syringe in any other way (For example, **Do not** warm it in a microwave or in hot water).
- **Do not** remove the prefilled syringe needle cover while allowing it to reach room temperature.



2.3 Check the Liquid in the Prefilled Syringe

- Hold your SIMPONI prefilled syringe by the body with the covered needle pointing down. See Figure 3.

Figure 3



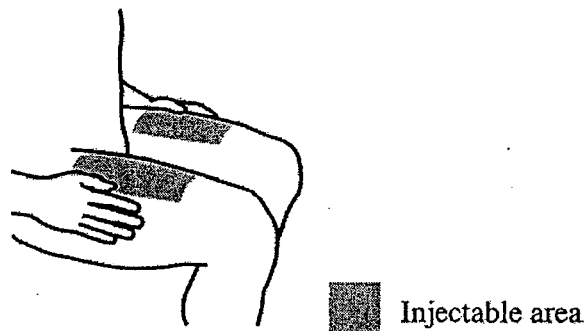
- Look at the liquid through the viewing window of the prefilled syringe. Make sure that the liquid in the prefilled syringe is clear and colorless to slightly yellow in color. You may see a small amount of tiny particles that are white, or that you can see through. Do not inject the liquid if it is cloudy or discolored, or has large particles in it.
- You may also see an air bubble. This is normal.

Step 3: Choose and prepare the injection site

3.1 Choose the Injection Site

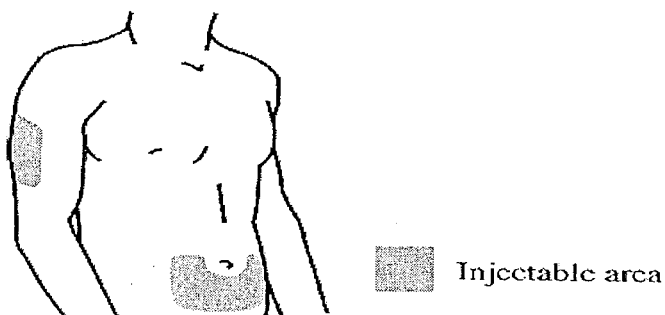
- The recommended injection site is the front of your middle thighs. See Figure 4.

Figure 4



- You can also use the lower part of the abdomen below the navel (belly button), except for the two-inch area directly around the navel. See Figure 5.
- If a caregiver is giving you the injection, the outer area of the upper arms may also be used. See Figure 5.

Figure 5



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

3.2 Prepare the Injection Site

- Wash your hands well with soap and warm water.
- Wipe the injection site with an alcohol swab.
- Do not touch this area again before giving the injection. Let your skin dry before injecting.
- Do not fan or blow on the clean area.

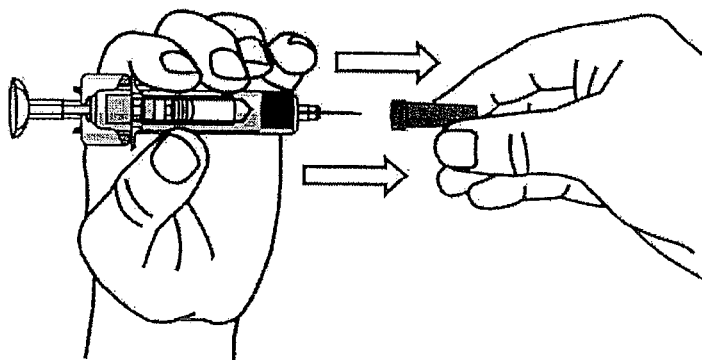
Step 4: Inject SIMPONI

Do not remove the needle cover until you are ready to inject SIMPONI. Inject SIMPONI within 5 minutes after you remove the needle cover.

4.1 Remove the Needle Cover

- Do not touch the plunger while removing the needle cover.
- Hold the body of the prefilled syringe with one hand, and pull the needle cover straight off. See Figure 6.

Figure 6

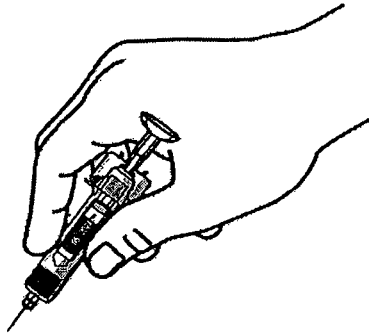


- Put the needle cover in the trash.
- You may see an air bubble in the prefilled syringe. This is normal.
- You may also see a drop of liquid at the end of the needle. This is normal.
- **Do not** touch the needle or let it touch any surface.
- **Do not** use the prefilled syringe if it is dropped without the needle cover in place.

4.2 Position the prefilled syringe and inject SIMPONI

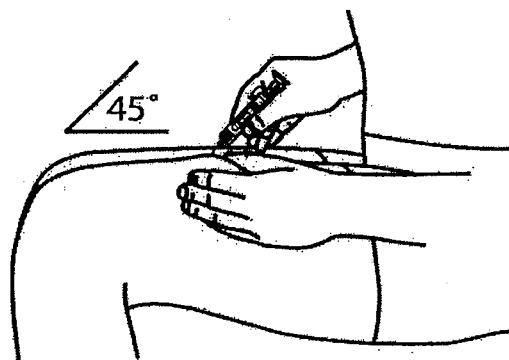
- Hold the body of the prefilled syringe in one hand between the thumb and index fingers. See Figure 7.

Figure 7



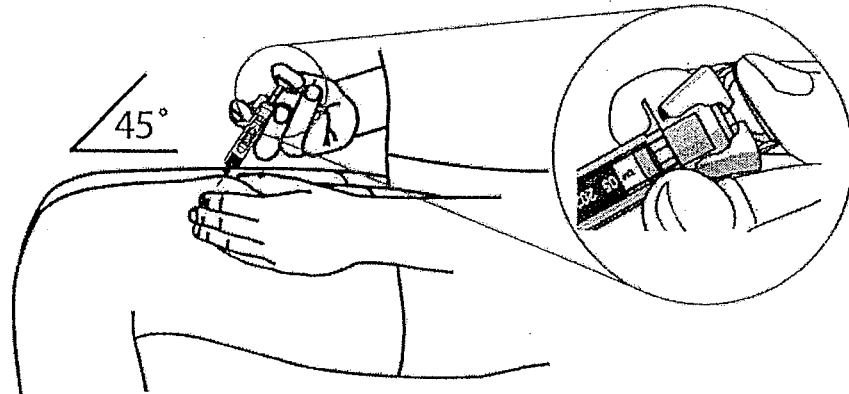
- **Do not** pull back on the plunger at any time.
- Use the other hand to gently pinch the area of skin that you previously cleaned. Hold firmly.
- Use a quick, dart-like motion to insert the needle into the pinched skin at about a **45-degree angle**. See Figure 8.

Figure 8



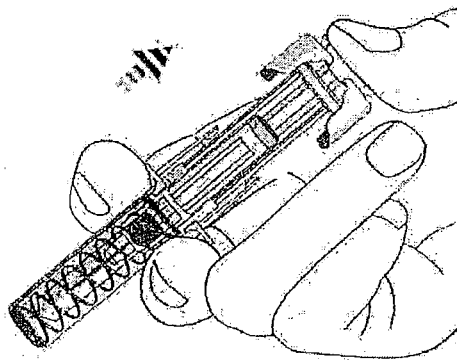
- Inject all of the medicine by using your thumb to push in the plunger until the plunger head is completely between the needle guard wings. See Figure 9.

Figure 9



- When the plunger is pushed as far as it will go, keep pressure on the plunger head. Take the needle out of the skin and let go of the skin.
- Slowly take your thumb off the plunger head. This will let the empty syringe move up until the entire needle is covered by the needle guard. See Figure 10.

Figure 10

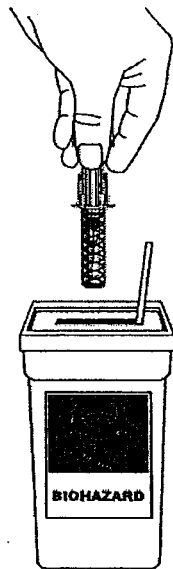


Step 5: After the injection

5.1 Dispose of the used prefilled syringe

- Place the used prefilled syringe in a closable puncture-resistant container. You may use a sharps container (such as a red biohazard container), a hard plastic container (such as a detergent bottle), or a metal container (such as an empty coffee can). For the safety and health of you and others, needles and used syringes **must never** be re-used. See Figure 11.

Figure 11



- Ask your doctor for instructions on the right way to throw away (dispose of) the container. There may be local or state laws about how you should throw away used needles and syringes.
- Do not throw away your used prefilled syringe in household trash. Do not recycle.

5.2 Use Cotton Ball or Gauze

- There may be a small amount of blood or liquid at the injection site, which is normal.
- You can press a cotton ball or gauze over the injection site and hold for 10 seconds. Do not rub the injection site.
- You may cover the injection site with a small adhesive bandage, if needed.

Manufactured by:
Centocor Ortho Biotech Inc.
Horsham, PA 19044
US License No. 1821

Revised: 4/2009

This Medication Guide has been approved by the U.S. Food and Drug Administration.