

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS



PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ORENCIA[®] 125 mg solution for subcutaneous injection (**abatacept**)

This formulation is not suitable for injection into a vein (IV injection).

Read all of this leaflet carefully before you start receiving ORENCIA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please contact your doctor or your pharmacist.
- ORENCIA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT ORENCIA CONTAINS

Each prefilled syringe of ORENCIA 125 mg solution for subcutaneous injection contains 125 mg abatacept.

The other ingredients are: anhydrous disodium phosphate, poloxamer 188, sodium phosphate monobasic monohydrate, sucrose, and water for injection.

WHAT ORENCIA IS USED FOR

ORENCIA is a medicine that is used to treat adults with active rheumatoid arthritis (RA)

ORENCIA solution for subcutaneous injection under the skin is not suitable for use in children younger than 18 years.

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BEFORE YOU RECEIVE ORENCIA**You should not receive ORENCIA:**

- if you are hypersensitive (allergic) to abatacept or any of the other ingredients of ORENCIA.
- if you have active or untreated tuberculosis (TB).
- if you are pregnant, or plan to become pregnant, or if you are breastfeeding your baby (see **Pregnancy and Breastfeeding**).

Tell your doctor or healthcare professional before you receive ORENCIA if you:

- are taking a TNF (tumour necrosis factor) blocker such as etanercept or infliximab to treat RA, as you have a greater chance of getting a serious infection if you use ORENCIA with other biologic medicines for RA.
- are taking anakinra.
- have any kind of infection including an infection that is in only one place in your body (such as an open cut or sore), or an infection that is in your whole body (such as the flu). Having an infection could put you at risk for serious side effects from ORENCIA. If you are unsure, please ask your doctor.
- have had tuberculosis (TB), a positive skin test for TB, or if you recently have been in close contact with someone who has had TB.
- develop any of the symptoms of TB (a dry cough that doesn't go away, weight loss, fever, night sweats) call your doctor right away. Before you start ORENCIA, your doctor should examine you for TB and perform a skin test.
- have a history of chronic obstructive pulmonary (lung) disease (COPD).
- are scheduled to have surgery.
- have cancer, your doctor will decide if you can still be given ORENCIA.
- recently received a vaccination or are scheduled for any vaccination.

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- have viral hepatitis. Before you start ORENCIA, your doctor may examine you for hepatitis.
- have human immunodeficiency virus (HIV) infection.

Pregnancy and Breastfeeding:

If you are pregnant, planning to become pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving ORENCIA.

ORENCIA should not be used in pregnancy or mothers breastfeeding their infants.

Driving and using machinery:

ORENCIA can make you feel dizzy and cause impaired vision. If you feel dizzy or have impaired vision you should not drive or operate machines.

Important information about some of the ingredients of ORENCIA

ORENCIA 125 mg solution for subcutaneous injection contains sucrose, which may have an effect on the control of your blood sugar if you have diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before you receive ORENCIA.

Using other medicines with ORENCIA:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines).

ORENCIA should not be used with biologic medications for RA, including TNF-blockers such as etanercept and infliximab. There is not enough evidence to recommend ORENCIA being given with anakinra.

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ORENCIA can be used with other medicines commonly used to treat RA, such as cortisone or painkillers, including non-steroidal anti-inflammatory medicines such as ibuprofen or diclofenac.

HOW TO RECEIVE ORENCIA

Do not share medicines prescribed for you with any other person.

You will receive ORENCIA as an injection under your skin (SC or subcutaneous). You will receive an injection once a week. Your doctor may start your treatment with a dose of ORENCIA lyophilisate for solution for intravenous infusion given to you in a vein in your arm over a period of 30 minutes. Your doctor will tell you how long your treatment with ORENCIA will last.

In the beginning, your doctor or healthcare professional may inject your ORENCIA solution for subcutaneous injection. However, you and your healthcare professional may decide that you may inject ORENCIA yourself. In this case you will receive training on how to inject ORENCIA yourself. You will find detailed ***“Instructions for preparing and giving a subcutaneous injection of ORENCIA”*** at the end of this leaflet.

ORENCIA solution for subcutaneous injection under the skin is not suitable for use in children younger than 18 years.

If you use more ORENCIA than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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If you missed a dose of ORENCIA

If you miss receiving ORENCIA when you are supposed to, ask your doctor when to schedule your next dose.

POSSIBLE SIDE EFFECTS

ORENCIA can have side effects.

Not all side effects reported for ORENCIA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving ORENCIA, please consult your doctor, pharmacist or other healthcare professional for advice.

ORENCIA can cause serious side effects. If any of the following happens, stop receiving ORENCIA and tell your doctor immediately, or go to the casualty department at your nearest hospital:

- **Serious infections. Patients receiving ORENCIA are at increased risk for developing infections including pneumonia, and other infections caused by viruses, bacteria, or fungi, including tuberculosis.**
- Allergic reactions. These reactions include hives, swollen face, eyelids, lips, tongue, throat, or difficult breathing.

Cancer (*malignancies*). There have been cases of certain kinds of cancer in patients receiving ORENCIA. The role of ORENCIA in the development of cancer is not known.

The more frequent side effects with ORENCIA are headache, upper respiratory tract infection, sore throat, and nausea.

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Tell you doctor or healthcare professional as soon as possible if you notice any of the following:

- feeling generally unwell, dental problems, burning sensation during urination, painful skin rash, painful skin blisters, coughing.

The symptoms described above can be signs of the side effects listed below, all of which have been observed with ORENCIA in adult clinical trials:

Frequent side effects

- infections of the upper airway (including infections of the nose and throat)
- infections of lungs, urinary infections, painful skin blisters (herpes), rhinitis
- headache, dizziness
- high blood pressure, flushing
- cough
- abdominal pain, diarrhoea, nausea, upset stomach
- rash
- fatigue, weakness
- abnormal liver function tests

Less frequent side effects

- tooth infection, nail fungal infection, collection of pus under the skin
- vaginal or oral thrush
- infection in and around your womb
- infection in your bladder
- skin cancer
- low blood platelet count, low white blood cell count
- depression, anxiety

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- numbness
- reduced vision, eye inflammation
- palpitation, rapid heart rate, low heart rate
- low blood pressure, hot flush
- gastrointestinal infections, mouth sores
- increased tendency to bruise, dry skin, hair loss
- painful joints, pain in extremities
- absence of menstruation
- flu-like illness, increased weight

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF ORENCIA

Protect the prefilled syringes from light by storing in the original package until time of use.

ORENCIA must be refrigerated at 2 °C to 8 °C.

Do not freeze ORENCIA.

Do not use after the expiry date stated on the container.

STORE ORENCIA AND ALL MEDICINES OUT OF THE REACH OF CHILDREN AND PETS.

Return unused medicine to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

Refer to the ***“Instructions for preparing and giving a subcutaneous injection of ORENCIA”*** at the end of this leaflet, for advice on how to dispose of prefilled syringes and needles.

APPROVED PATIENT INFORMATION LEAFLET**PRESENTATION OF ORENCIA**

ORENCIA solution for subcutaneous injection is supplied as a sterile, preservative-free, ready-to-use solution for injection under the skin. The injection solution is supplied either:

- in a single-dose disposable prefilled glass syringe with a passive needle safety guard and flange extenders, or
- in a single-dose disposable prefilled glass syringe with flange extenders.

The Type I glass syringe has a coated stopper and fixed stainless steel needle covered with a rigid needle shield. A sufficient excess of abatacept is included into each syringe to account for needle-syringe losses so that 1,0 ml of solution containing 125 mg abatacept can be injected under the skin. Both presentations are packed in cartons containing four pre-filled syringes.

IDENTIFICATION OF ORENCIA

ORENCIA solution for subcutaneous injection: Clear, colourless to pale yellow, slightly opalescent solution, essentially free from visible particles.

REGISTRATION NUMBER

To be allocated by Council upon registration.

NAME AND ADDRESS OF REGISTRATION HOLDER

Equity Pharmaceuticals (Pty) Ltd

100 Sovereign Drive

Route 21 Corporate Park

Nellmapius Drive

Irene

Pretoria, 0157

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**INSTRUCTIONS FOR PREPARING AND GIVING A SUBCUTANEOUS INJECTION OF
ORENCIA**

The following instructions explain how to give yourself an injection of ORENCIA using the prefilled syringe or the prefilled syringe with needle guard. Please read the instructions carefully and follow them step by step. You will be instructed by your doctor, nurse or healthcare professional on the technique of self-injection. Do not attempt to self-inject until you are sure that you understand how to prepare and give the injection. After proper training, the injection can be self-administered or given by another person, for example a family member or friend.

ORENCIA prefilled syringe with needle guard:

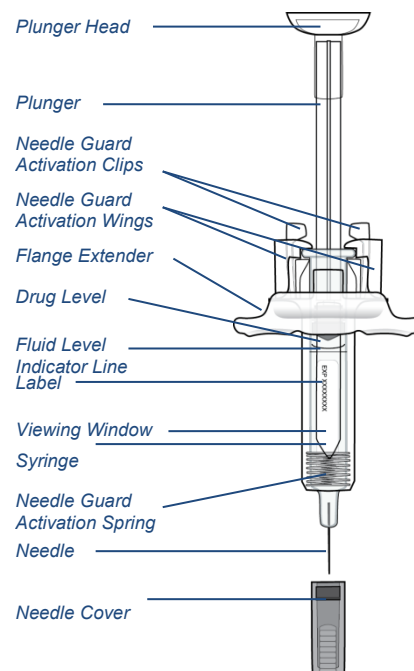


Figure 1a

- Always handle the syringe carefully, especially when you are around other people, children and animals.

Before you use ORENCIA prefilled syringe with needle guard

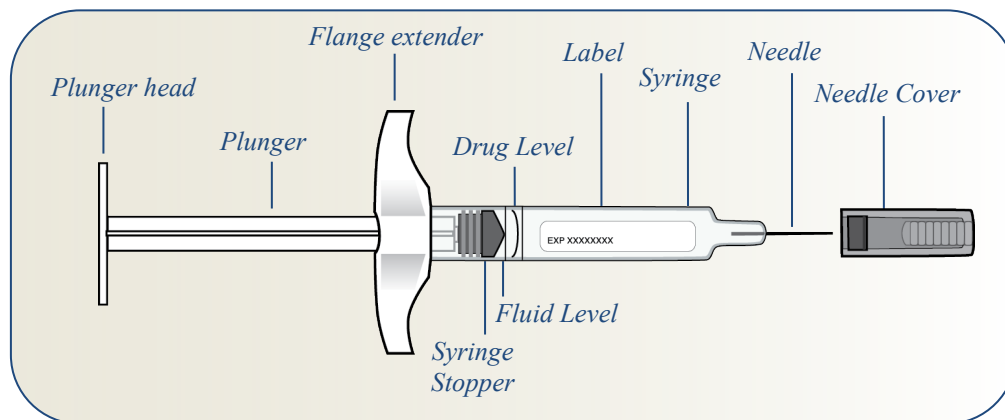
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Do

- Always hold the syringe by its body.
- Store unused syringes in the refrigerator in the original carton.
- Have your additional injection supplies ready prior to injection.
 - Supplies checklist: Alcohol swab, cotton ball or gauze, adhesive bandage, and Sharps container.

Don't

- Do not pull by the plunger or the needle cover when removing the syringe from the tray.
- Do not remove the needle cover until you are ready to inject.
- Do not pull back on the plunger at any time.
- Do not shake the ORENCIA syringe, as this may damage the medicine.

ORENCIA prefilled syringe:**Figure 1b**

- Always handle the syringe carefully, especially when you are around other people, children and animals.

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Before you use ORENCIA prefilled syringe**Do**

- Always hold the syringe by its body.
- Store unused syringes in the refrigerator in the original carton.
- Have your additional injection supplies ready prior to injection.
 - Supplies checklist: Alcohol swab, cotton ball or gauze, adhesive bandage, and Sharps container.

Don't

- Do not remove the needle cover until you are ready to inject.
- Do not pull back on the plunger at any time.
- Do not shake the ORENCIA syringe, as this may damage the medicine.
- **DO NOT** recap used needle.

STEP 1: Get your syringe ready

A. Check the expiration date

- The expiration date can be found on the ORENCIA carton and on each syringe.
- If the expiration date has passed, do not use the prefilled syringe. Please contact your doctor or pharmacist for assistance.

B. Let it warm up for 30 to 60 minutes

- Find a comfortable space with a clean, flat working surface.
- Prefilled syringe with needle guard: To properly remove the syringe from the package, grasp the body as indicated by the arrows in the tray.
- Remove the syringe from the refrigerator. Keep remaining unused syringes in their original carton and keep in refrigerator.
- Inspect the syringe for obvious flaws, **but do not remove needle cover**.

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- Allow the syringe to rest at room temperature for at least 30 to 60 minutes prior to injection.
 - **Do not** speed the warming process in any way, such as using the microwave or placing the syringe in warm water.

C. Check the liquid in the prefilled syringe with needle guard

- Hold your ORENCIA prefilled syringe by the body with the covered needle pointing down.

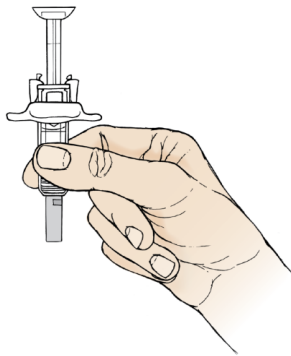


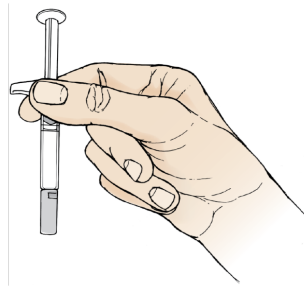
Figure 2a

- Look at the liquid through the viewing window of your prefilled syringe (see Figure 2a). The liquid in your syringe should be clear to pale yellow. Do not inject if the liquid is cloudy, discoloured, or has large particles.
- It is normal to see an air bubble, and there is no reason to remove it. All contents of the syringe should be injected.

C. Check the liquid in the prefilled syringe

- Hold your ORENCIA prefilled syringe by the body with the covered needle pointing down.

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**Figure 2b**

- Look at the liquid through the viewing window of your prefilled syringe (see Figure 2b). The liquid in your syringe should be clear to pale yellow. Do not inject if the liquid is cloudy, discoloured, or has large particles.
- It is normal to see an air bubble, and there is no reason to remove it. All contents of the syringe should be injected.

D. Gather your additional supplies and keep them within easy reach.

E. Wash your hands thoroughly with soap and warm water.

STEP 2: Choose and prepare a section on your body for the injection (injection site)

Have your ORENCIA prefilled syringe with needle guard or your ORENCIA prefilled syringe ready for use immediately after preparing the injection site.

A. Choose your injection site

- The front of the thigh is a recommended injection area. You may use your abdomen except for the 5 cm area around the navel (see Figure 3).
- The outer area of the upper arms may also be used only if the injection is being given by a caregiver. Do not attempt to use the upper arm area by yourself (see Figure 4).

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- Choose a different injection site for each new injection. You may use the same thigh for weekly injections, as long as each injection is approximately 2,5 cm apart from the last time you injected yourself in that area.
- Do not inject into areas where your skin is tender, bruised, red, scaly, or hard. Avoid any areas with scars or stretch marks.

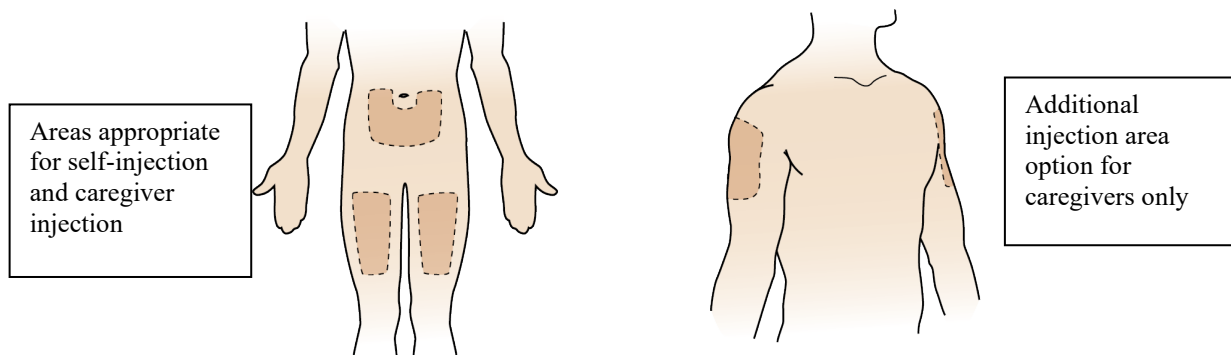


Figure 3

Figure 4

B. Prepare your injection site

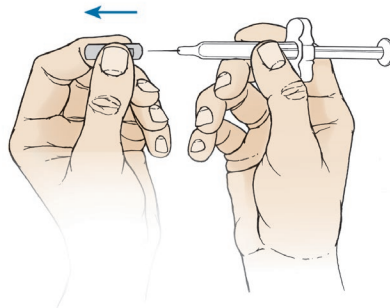
- Wipe the injection site with an alcohol swab in a circular motion.
- Let your skin dry before injecting. Do not touch the injection site again before giving the injection.
- Do not fan or blow on the clean area.

STEP 3: Inject ORENCIA prefilled syringe with needle guard

A. Remove the needle cover.

- Do not touch the plunger while you remove the needle cover.
- Hold the body of the ORENCIA prefilled syringe with one hand and pull the needle cover straight off with your other hand (see Figure 5a).
- **Do not remove the needle cover until you are ready to inject ORENCIA. Inject ORENCIA as soon as possible after removing the needle cover.**

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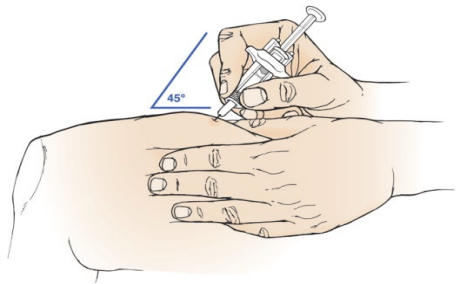
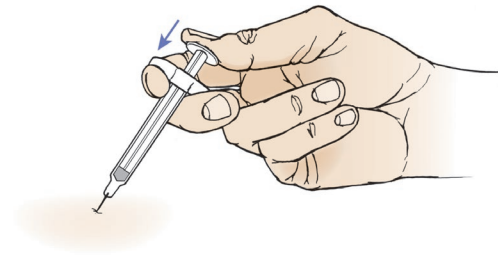
**Figure 5a**

- There may be a small air bubble in the syringe tube containing the medication. There is no need to remove the air bubble.
- You may notice a drop of fluid leaving the needle. This is normal and will not affect your dose.
- Do not touch the needle or let it touch any surfaces.
- Do not use the prefilled syringe if it is dropped without the needle cover in place.

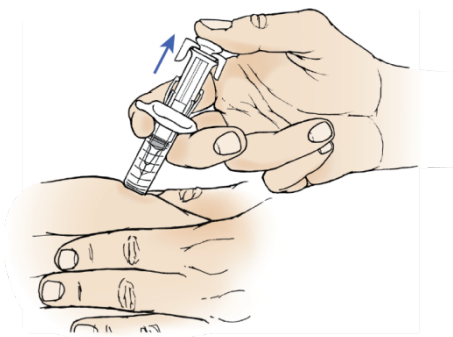
B. Position the prefilled syringe and inject ORENCIA

- Hold the body of your prefilled syringe in one hand between the thumb and index finger (see Figure 6a).
- Do not apply pressure to the plunger head until you are ready to begin your injection.
- Do not pull back on the plunger of the syringe at any time.
- Use your other hand and gently pinch the area of skin you cleaned. Hold firmly.
- Use a quick, dart-like motion to insert the needle into the pinched skin at a 45° angle (see Figure 6a).

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**Figure 6a****Figure 7a**

- To inject all of the medicine, use your thumb to push the plunger until the plunger head is completely between the needle guard sides (see Figure 7a).
- When the plunger is pushed in as far as it will go, continue to apply pressure to the plunger head.
- Slowly lift your thumb from the plunger head. This allows the empty syringe to move up until the entire needle is covered by the needle guard (see Figure 8).

**Figure 8**

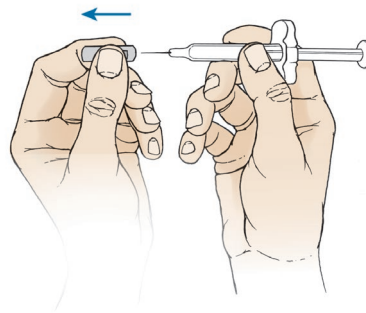
- Once the needle is completely covered by the needle guard, remove it and let go of the surrounding skin.
- Press a cotton ball over the injection site and hold for 10 seconds.
 - Do not rub the injection site. Slight bleeding is normal.
 - If needed, you may apply a small adhesive bandage to the injection site.

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STEP 3: Inject ORENCIA prefilled syringe

A. Remove the needle cover.

- Do not touch the plunger while you remove the needle cover.
- Hold the body of the ORENCIA prefilled syringe with one hand and pull the needle cover straight off with your other hand (see Figure 5b).
- **Do not remove the needle cover until you are ready to inject ORENCIA. Inject ORENCIA as soon as possible after removing the needle cover.**

**Figure 5b**

- There may be a small air bubble in the syringe tube containing the medication. There is no need to remove the air bubble.
- You may notice a drop of fluid leaving the needle. This is normal and will not affect your dose.
- Do not touch the needle or let it touch any surfaces.
- Do not use the prefilled syringe if it is dropped without the needle cover in place.

B. Position the prefilled syringe and inject ORENCIA

- Hold the body of your prefilled syringe in one hand between the thumb and index finger (see Figure 6b).
- Do not apply pressure to the plunger head until you are ready to begin your injection.

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- Do not pull back on the plunger of the syringe at any time.
- Use your other hand and gently pinch the area of skin you cleaned. Hold firmly.
- Use a quick, dart-like motion to insert the needle into the pinched skin at a 45° angle (see Figure 6b).

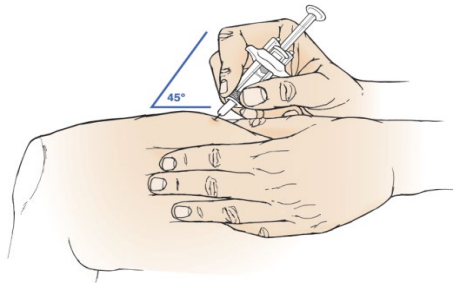


Figure 6b

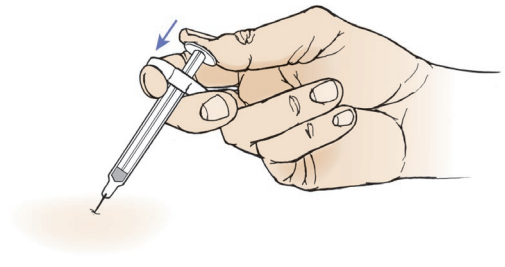


Figure 7b

- To inject all of the medicine, use your thumb to push the plunger until the plunger head completely bottoms out and is pushed in as far as it will go. Remove the needle from the skin and let go of the surrounding skin (see Figure 7b).
- **DO NOT** recap needle.
- Press a cotton ball over the injection site and hold for 10 seconds.
 - Do not rub the injection site. Slight bleeding is normal.
 - If needed, you may apply a small adhesive bandage to the injection site.

STEP 4: Disposal and recordkeeping

A. Dispose of your used syringe in a Sharps container.

- Be careful when discarding the prefilled syringe after use.
- Sharps containers are special puncture-resistant disposal bins that can be purchased at many retail outlets.

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**Sharps Container**

- Always keep your Sharps container out of reach of children and animals.
- Ask your doctor, nurse, or pharmacist about state and local laws regarding the proper disposal of medical products that contain needles.
- Do not throw away your used prefilled syringes in your household waste, drains or recycling bins.

B. Record your injection

- Write down the date, time, and specific part of your body where you injected yourself. It may also be helpful to write down any questions or concerns about the injection so you can ask your doctor, nurse or pharmacist.