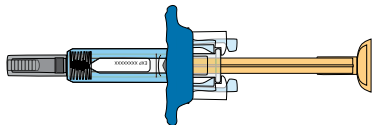


# HOW TO TAKE ORENCIA

## Instructions for injecting the ORENCIA prefilled syringe with BD UltraSafe Passive™ Needle Guard

Read these instructions before you start taking ORENCIA



Consider rereading each time you get a refill—there may be new information.

Before you use the prefilled syringe for the first time, make sure your healthcare provider shows you the right way to use it and decides that you or a caregiver may be able to give your injections of ORENCIA at home.



### Indications/Usage

**Adult Rheumatoid Arthritis (RA):** ORENCIA® (abatacept) is a prescription medicine that reduces signs and symptoms in adults with moderate to severe RA, including those who have not been helped enough by other medicines for RA. ORENCIA may prevent further damage to your bones and joints and may help your ability to perform daily activities. In adults, ORENCIA may be used alone or with other RA treatments other than Janus kinase (JAK) inhibitors or biologic disease-modifying antirheumatic drugs (bDMARDs), such as tumor necrosis factor (TNF) antagonists.

**Polyarticular Juvenile Idiopathic Arthritis (pJIA):** ORENCIA reduces signs and symptoms in patients 2 years of age and older with moderate to severe polyarticular JIA. ORENCIA may be used alone or with methotrexate (MTX).

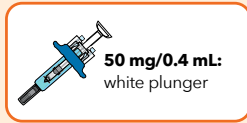
**Adult Psoriatic Arthritis (PsA):** ORENCIA is a prescription medicine that reduces signs and symptoms in adults with active psoriatic arthritis (PsA). In adults, ORENCIA may be used alone or with other PsA treatments.

The concomitant use of ORENCIA with other potent immunosuppressants [e.g., bDMARDs, JAK inhibitors] is not recommended.

Please read Important Safety Information on pages 20-23.

# Getting to know your prefilled syringe

There are 3 types of prefilled syringes:



The type of prefilled syringe you receive depends on the dose prescribed by your healthcare provider.

## How to store your prefilled syringe

- Store your prefilled syringe in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Keep your prefilled syringe in the original package and out of the light.
- Safely throw away medicine that is out of date or no longer needed.

### Important:

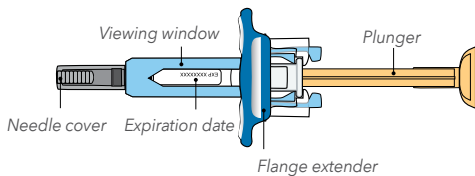
- Keep the prefilled syringe in the refrigerator until ready to use.
- DO NOT freeze.

## Your prefilled syringe before and after use

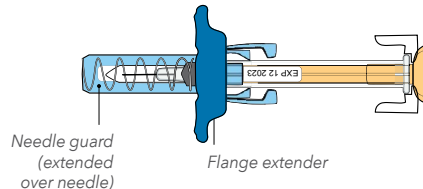
The 125 mg/mL prefilled syringe is shown below.

The prefilled syringe has a **flange extender** that makes it easier to hold and inject, and a **needle guard** that automatically covers the needle after a complete injection.

### Before Use



### After Use



### Important:

- DO NOT remove the needle cover until you are ready to inject.
- DO NOT PULL back on the plunger at any time.
- DO NOT RECAP the prefilled syringe at any time, as this may damage, bend, or break the needle.

Go to Step 1 ▶

# Step 1: Prepare for your injection

## Remove your syringe from the refrigerator and wait 30 minutes

Remove one prefilled syringe from the refrigerator and wait 30 minutes to allow it to reach room temperature.

### Important:

- DO NOT speed up the warming process in any way, such as using the microwave or placing the syringe in warm water.
- DO NOT remove the needle cover while allowing the prefilled syringe to reach room temperature.



## Gather supplies for your injection on a clean, flat surface

Only the prefilled syringe is included in the package.

You'll need:

- Prefilled syringe with UltraSafe Passive Needle Guard



- Sharps disposal container



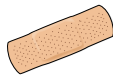
- Alcohol swab



- Cotton ball or gauze

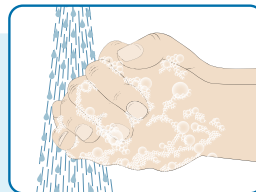


- Adhesive bandage



## Wash your hands

Wash your hands well with soap and water.



## Step 2: Examine your prefilled syringe

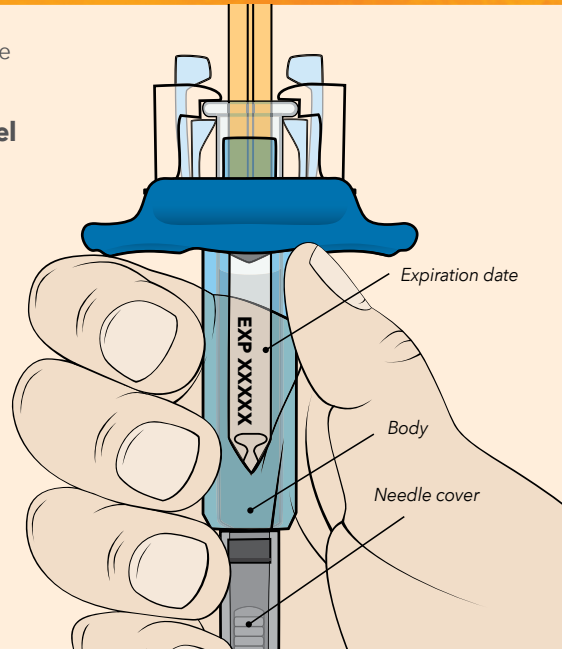
Hold the prefilled syringe by the body with the needle cover pointing down as shown.

### Check the expiration date printed on the label

DO NOT use if the expiration date has passed.

### Check the prefilled syringe for damage

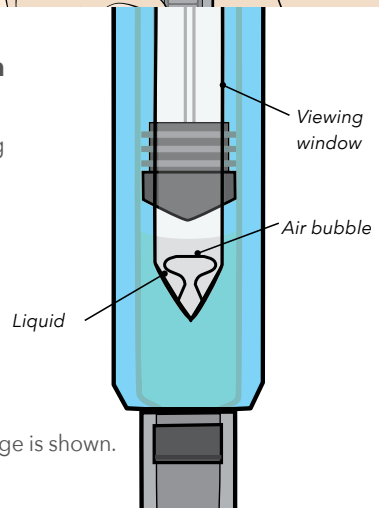
DO NOT use if it is cracked or broken.



### Check the liquid in the prefilled syringe through the viewing window

Check the liquid in the prefilled syringe through the viewing window. It should be clear and colorless to pale yellow. Do not inject if the liquid is cloudy, discolored, or has particles in it.

It is normal to see an air bubble. Do not attempt to remove it.

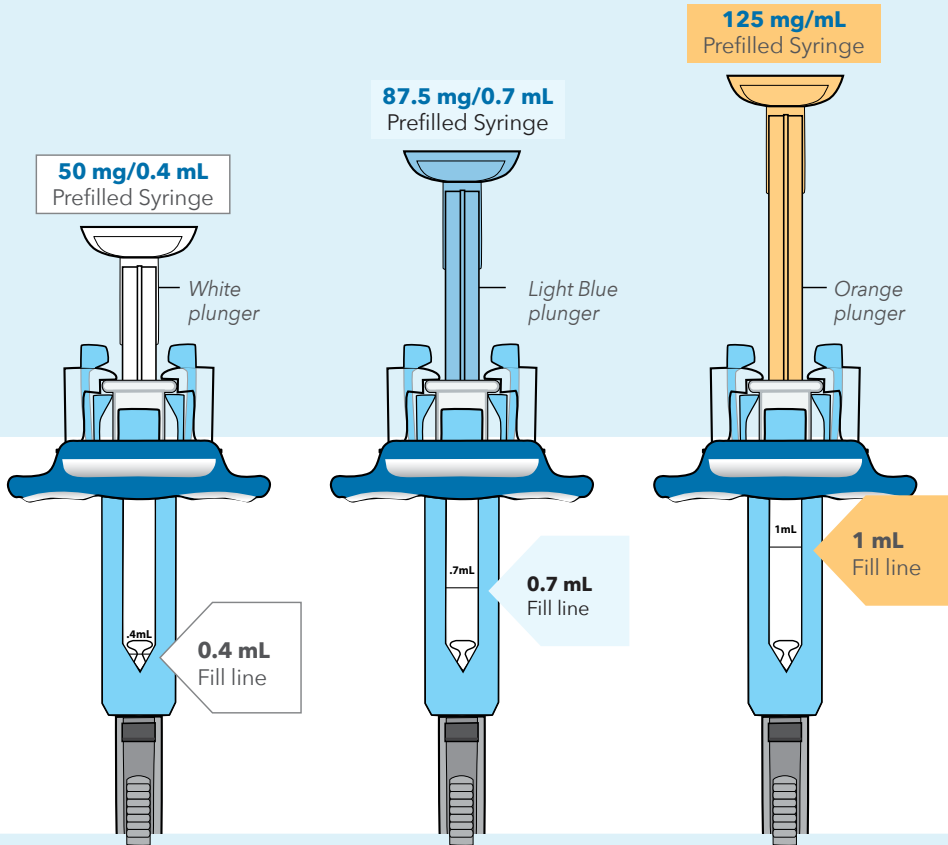


The 50-mg prefilled syringe is shown.

# Step 3: Check the dose on your prefilled syringe

## Hold the syringe at eye level

Look closely to make sure that the amount of liquid in the prefilled syringe is at or just above the fill line for your prescribed dose:



### Important:

- DO NOT use if your prefilled syringe does not have the correct amount of liquid. Call your pharmacist immediately.

# Step 4: Choose and prepare your injection site

## Choose your injection site

You can choose to inject in:

- The stomach (abdomen)
- Front of the thighs
- Outer area of upper arm (only if your caregiver is administering your dose)

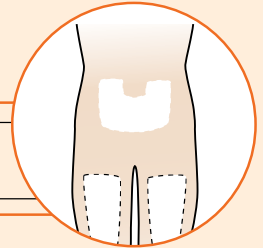
## Rotate your injection site

- Each week you can use the same area of your body, but use a different injection site in that area.
- DO NOT inject into an area where the skin is tender, bruised, red, scaly, or hard.
- DO NOT give the injection in any areas with scars or stretch marks.
- Record the date, time, and site where you inject.

### Injection Areas:

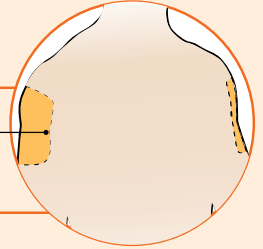
Self-Injection  
and Caregiver

Abdomen,  
avoid 2 inches  
around navel  
Front of thighs



Caregiver ONLY

Outer area of  
upper arms



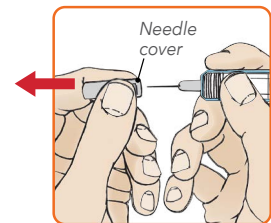
## Gently clean your injection site

Wipe the injection site with an alcohol swab and let it air dry.

- DO NOT touch the injection site again before giving the injection.
- DO NOT fan or blow on the clean area.

## Remove the needle cover

Hold the body of the prefilled syringe with one hand and pull the cover straight off with your other hand.



## Important:

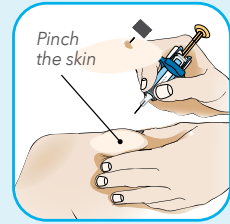
- DO NOT put the needle cover back on the needle after you remove it. Throw away the needle cover in your household trash.
- DO NOT use the prefilled syringe if it is dropped after the needle cover is removed.
- DO NOT use the prefilled syringe if the needle is damaged or bent.
- DO NOT recap the prefilled syringe, as this may damage the needle.

Note: It is normal to see a drop of fluid leaving the needle.

# Step 5: Inject your dose

## Pinch your skin

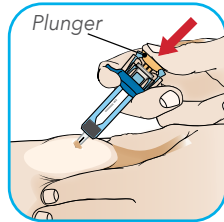
Hold the body of the prefilled syringe in your hand using your thumb and index finger. With your other hand, pinch the area of skin you cleaned.



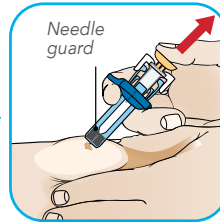
## Inject your dose



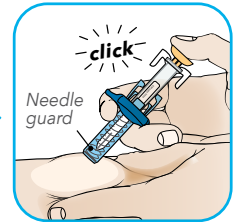
**Insert:** Gently insert the needle into the pinched skin at a 45° angle.



**Inject:** Push the plunger with your thumb as far as it will go.



**Release Needle Guard:** Slowly lift your thumb from the plunger to activate the needle guard.



**Confirm:** After a complete injection, the needle guard will cover the needle and you may hear a click.

Remove the prefilled syringe and let go of the pinched skin. Complete all steps to deliver your full dose of the medicine.

# Step 6: After the injection

## Care for the injection site

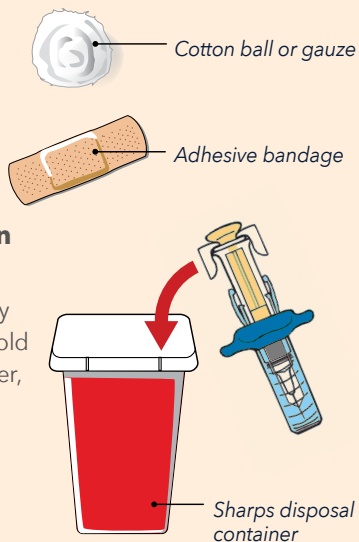
There may be a little bleeding at the injection site. You can press a cotton ball or gauze over the injection site. If needed, you may cover the injection site with an adhesive bandage.

- DO NOT rub the injection site.

## Dispose of your used prefilled syringe after injection

Put your used ORENCIA 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 a heavy-duty plastic
- Leak resistant
- Equipped with a tight-fitting, puncture-resistant lid, without sharps being able to come out
- Properly labeled to warn of hazardous waste inside the container
- Upright and stable during use



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 and syringes. 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>.

## Important:

- DO NOT throw away (dispose of) **loose needles and prefilled syringes** in your household trash.
- DO NOT throw away (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.

See Frequently Asked Questions for additional disposal information.

If your injection is administered by a caregiver, this person must also be careful handling the syringe to prevent accidental needle stick injury and possibly spreading infection.

**Keep ORENCIA® (abatacept) prefilled syringes and the disposal container out of the reach of children.**



# Frequently Asked Questions

**Q. Why do I need to allow the prefilled syringe to warm up at room temperature for 30 minutes prior to injecting?**

A. This step is primarily for your comfort. Never try to speed up the warming process in any way, like using the microwave or placing the syringe in warm water.

**Q. Is it necessary to hold the skin pinch during the entire time I inject the dose?**

A. You must pinch the skin during needle insertion; however, for your comfort you may release the skin pinch as you deliver the injection.

**Q. What if my prefilled syringe appears to be broken or damaged?**

A. Do not use the prefilled syringe. Contact your healthcare provider or pharmacist for further instructions.

**Q. What if I cannot clearly see the liquid inside the syringe?**

A. Look at the syringe closely by holding at eye level and up to the light. You may tilt the syringe slowly to get a better view of the drug fluid. If you still have trouble, contact your healthcare provider or pharmacist for further instructions.

**Q. Is it normal to feel a little bit of burning or pain during injection?**

A. You may feel a prick from the needle. Sometimes, the medicine can cause slight irritation near the injection site. Discomfort should be mild to moderate. If you have any side effects, including pain, swelling, or discoloration near the injection site, contact your healthcare provider.

# Frequently Asked Questions

## **Q. How should I dispose of a used prefilled syringe?**

A. Place the used prefilled syringe into an FDA-cleared sharps disposal container.

If you do not have one you may use a household container that is:

- Made of a heavy-duty plastic.
- Equipped 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 and injector pens. 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>.

## **Q. How should I keep my prefilled syringes cool while traveling?**

A. Store them in a cool carrier between 36°F to 46°F (2°C to 8°C).

Do not freeze them. Keep them in the original carton and protected from light.

Your healthcare provider may know about special carrying cases.

## **Q. Can I take my prefilled syringes on an airplane?**

A. Generally you are allowed to carry your prefilled syringes with you on an airplane. Do not put them in your checked luggage. You should carry your prefilled syringes with you in your travel cooler at a temperature of 36°F to 46°F (2°C to 8°C). Keep your prefilled syringes in the original carton, and with its original preprinted labels and protected from light.

## **Q. What if my prefilled syringe does not stay cool for an extended period of time?**

### **Is it dangerous to use?**

A. Contact 1-800-ORENCIA (1-800-673-6242) for more information.

**If you have questions or concerns about your prefilled syringe, please contact your healthcare provider or call our toll-free help line at 1-800-ORENCIA (1-800-673-6242).**

# Important Safety Information

Inform your healthcare provider of the following, before you receive treatment with ORENCIA® (abatacept):

**Infections:** If you have any kind of infection, even if it is small (such as an open cut or sore), an infection that is in your whole body (such as the flu), an infection that will not go away, or a history of infections that keep coming back. ORENCIA may make your immune system less able to fight infections, so you may be more likely to get infections or any infection you have may get worse.

**Tuberculosis:** If you 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. If you get any of the symptoms of TB (a cough that does not go away, weight loss, fever, night sweats), call your healthcare provider right away. Before you start ORENCIA, your healthcare provider may examine you for TB or perform a skin test.

If you have or have had **Viral Hepatitis**. Before you use ORENCIA, your healthcare provider may examine you for hepatitis.

If you have a history of **Chronic Obstructive Pulmonary (lung) Disease (COPD)**.

If you are scheduled to have **Surgery**.

**Allergies to the Ingredients of ORENCIA:** The ingredients of intravenous (IV) ORENCIA are: abatacept, maltose, monobasic sodium phosphate, and sodium chloride for administration. The ingredients of subcutaneous (SC) ORENCIA are: abatacept, sucrose, poloxamer 188, monobasic sodium phosphate monohydrate, dibasic sodium phosphate anhydrous, and water for injection.

**Vaccinations:** If you have recently received a vaccination or are scheduled for any vaccination. If you are receiving ORENCIA, and for 3 months after you stop receiving ORENCIA, you should not take live vaccines.

**Please see additional Important Safety Information on the next page.**

**Diabetes:** If you have diabetes and use a blood glucose monitor to check your sugar levels. The **infusion** of ORENCIA® (abatacept) contains maltose, a sugar that can give falsely high blood glucose readings with some monitors on the day you receive your infusion. Your healthcare provider may tell you to use a different way to monitor your blood sugar levels. ORENCIA for SC injection does not contain maltose; therefore, you do not need to change the way you monitor your blood sugar if you are taking ORENCIA subcutaneously.

**Pregnancy:** If you are pregnant, or plan to become pregnant. It is not known if ORENCIA can harm your unborn baby. If you took ORENCIA during pregnancy, talk to your healthcare provider before your baby receives any vaccines.

There is a registry for pregnant women exposed to ORENCIA. The purpose of this registry is to check the health of the pregnant mother and her child. Women are encouraged to call the registry themselves or ask their healthcare provider to contact the registry for them by calling 1-877-311-8972.

**Breastfeeding:** It is not known if ORENCIA passes into your breastmilk. Talk to your healthcare provider about the best way to feed your baby if you use ORENCIA.

**Skin cancer:** Some people treated with ORENCIA have developed skin cancer. Tell your healthcare provider if you have a family or personal history of skin cancer, and if you see any growths or changes in the appearance of your skin during or after your treatment with ORENCIA.

If you **Take Any Other Kinds of Medicine**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**Please see additional Important Safety Information on the next page.**

# Important Safety Information (cont.)

If you are **Taking Other Biologic Medicines** such as: Enbrel® (etanercept), Humira® (adalimumab), Remicade® (infliximab), Kineret® (anakinra), Rituxan® (rituximab), Simponi® (golimumab), Cimzia® (certolizumab pegol), or Actemra® (tocilizumab). You may have a higher chance of getting a serious infection if you take ORENCIA® (abatacept) with other biologic medicines.

## Possible Side Effects of ORENCIA

**ORENCIA can cause serious side effects including:**

- **Serious infections.** ORENCIA can make you more likely to get infections or make the infection that you have get worse. Some people have died from these infections. Call your healthcare provider immediately if you feel sick or get any of the following signs of infection: fever; feel very tired; cough; feel flu-like; or warm, red or painful skin.
- **Allergic reactions.** Allergic reactions can happen to people who use ORENCIA. Call your healthcare provider or get emergency medical help right away if you have any symptoms of an allergic reaction, which may include hives; swollen face, eyelids, lips, or tongue; or trouble breathing.
- **Hepatitis B infection.** If you are a carrier of the hepatitis B virus (a virus that affects the liver), the virus can become active while you use ORENCIA. Your healthcare provider may do a blood test before you start treatment with ORENCIA.
- **Vaccinations.** You should not receive ORENCIA with certain types of vaccines (live vaccines). You can receive non-live vaccines, such as pneumococcal and inactivated influenza (flu) vaccines. ORENCIA may cause some vaccinations to be less effective. Talk to your healthcare provider about your vaccination plans.

**Please see additional Important Safety Information on the next page.**

- **Respiratory problems in people with COPD.** You may get certain respiratory problems more often if you receive ORENCIA® (abatacept) and have COPD, including: worsened COPD, cough, or trouble breathing.
- **Cancer (malignancies).** Certain kinds of cancer have been reported in people receiving ORENCIA. It is not known if ORENCIA increases your chance of getting certain kinds of cancer.

**Common side effects** with ORENCIA are headache, upper respiratory tract infection, sore throat, and nausea. Other side effects in children and adolescents may include diarrhea, cough, fever, and abdominal pain.

These are not all the possible side effects of ORENCIA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

There are three ways to receive your dose of ORENCIA, and each way is approved for different ages:

- ORENCIA prefilled SC syringe is approved for patients 2 years and older.
- ORENCIA IV is approved for patients 6 years and older. ORENCIA IV has not been studied in children younger than 6 years of age.
- P/JIA patients may self-inject with ORENCIA or the patient's caregiver may administer ORENCIA if both the healthcare practitioner and the parent/legal guardian determines it is appropriate. The ability of pediatric patients to self-inject with the ClickJect Autoinjector has not been tested.

Please talk to your healthcare provider about the best way to receive ORENCIA.

**Please read the Patient Information in the Full Prescribing Information enclosed in the Welcome Kit.**

## Have you signed up for ORENCIA On Call™ yet?

ORENCIA On Call™ is a patient support program that's dedicated to helping people who are taking ORENCIA. By signing up, you could receive:

Sharps disposal service	Treatment journal	Travel cold case
You'll receive an approved container to dispose of your syringes and you can send it back once it's full.	You can keep track of when you need to take ORENCIA and when to rotate the injection site.	You can keep your syringes at the right temperature for up to 6 hours.*

Sign up by visiting [ORENCIA.com](http://ORENCIA.com) or call **1-800-ORENCIA (1-800-673-6242)**.

**Please read the Patient Information in the Full Prescribing Information enclosed in the Welcome Kit.**

\*Please refer to full Travel Cold Pack instruction for proper use.



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