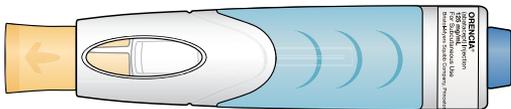


HOW TO TAKE ORENCIA

Instructions for injecting the ORENCIA ClickJect™ Autoinjector

125 mg/mL, single-dose Autoinjector, for subcutaneous use only

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 Autoinjector for the first time, make sure your healthcare provider shows you the right way to use it.



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.

Psoriatic Arthritis (PsA): ORENCIA® (abatacept) is a prescription medicine that reduces signs and symptoms in patients 2 years of age and older with active psoriatic arthritis (PsA). In adults, ORENCIA may be used alone or with other non-biologic PsA treatments. In children, ORENCIA can be used alone or with methotrexate

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

It is not known if ORENCIA is safe and effective in children less than two years of age for the treatment of PsA.

Getting to know your ClickJect™ Autoinjector

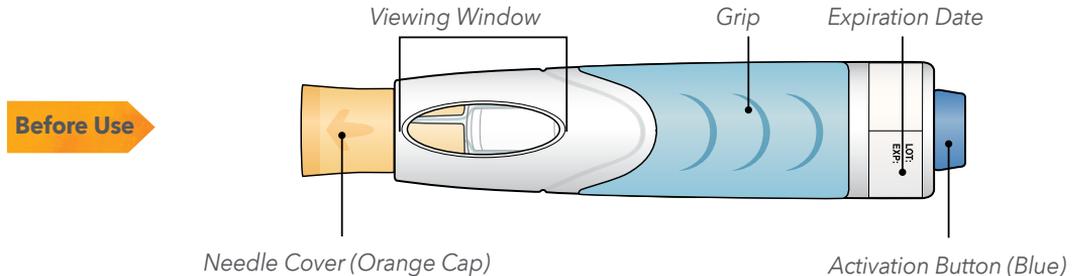
How to store your Autoinjector

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- Safely throw away medicine that is out of date or no longer needed

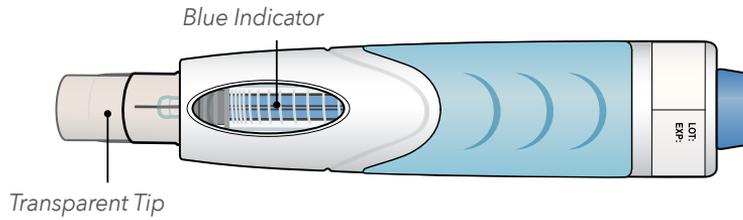
Important:

- Keep the ClickJect™ Autoinjector in the refrigerator until ready to use
- DO NOT freeze
- DO NOT remove the orange needle cover until you are ready to inject

The Autoinjector automatically delivers the medicine. The transparent tip locks over the needle once the injection is complete and the Autoinjector is removed from the skin.



After Use



Step 1: Prepare for your injection

Remove your Autoinjector from the refrigerator and wait 30 minutes

Remove one Autoinjector from the refrigerator and let it rest at room temperature for 30 minutes.

Important:

- DO NOT remove the Autoinjector needle cover while allowing it to reach room temperature



Gather supplies for your injection on a clean, flat surface

Only the ClickJect™ Autoinjector is included in the package.

You'll need:

- ClickJect™ Autoinjector



- Alcohol swab



- Adhesive bandage



- Sharps disposal container



- Cotton ball or gauze



Wash your hands

Wash your hands well with soap and water.



Examine your Autoinjector

- **Check expiration date printed on the label**

DO NOT use if past the expiration date.

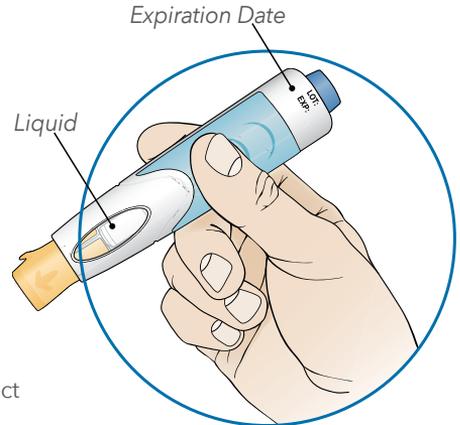
- **Check the Autoinjector for damage**

DO NOT use if it is cracked or broken.

- **Check the liquid 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.

You may see a small air bubble. You do not need to remove it.



Step 2: Choose and prepare your injection site

Choose your injection site

You can choose to inject in:

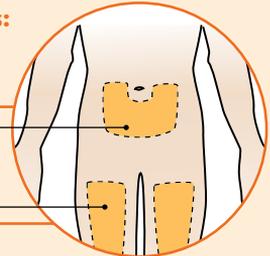
- The stomach (abdomen)
- Front of the thighs
- Outer area of upper arm (only if your caregiver is administering your dose)

Injection Areas:

Self-Injection and Caregiver:

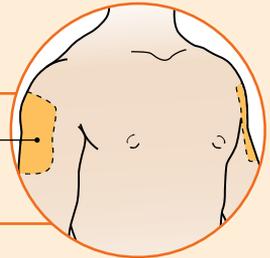
Abdomen,
avoid 2 inches
around navel

Front of thighs



Caregiver ONLY

Outer area of
upper arms



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

Gently clean your injection site

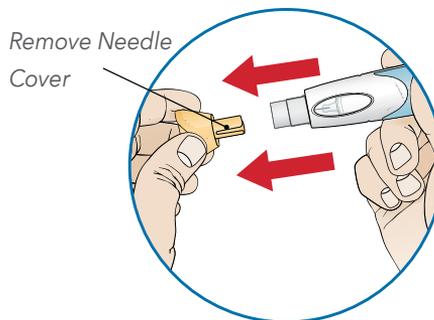
Wipe the injection site with an alcohol swab and let it air dry.

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

Pull orange needle cover straight off

- DO NOT TWIST the needle cover
- DO NOT RECAP the Autoinjector
- Throw away (discard) the needle cover in your household trash
- DO NOT use the Autoinjector if it is dropped after the needle cover is removed

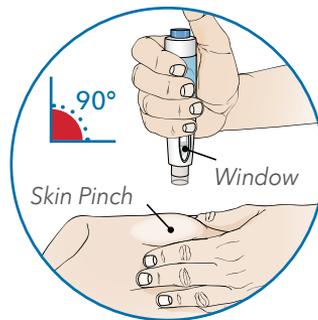
Note: It is normal to see a drop of fluid leaving the needle.



Step 3: Inject your dose

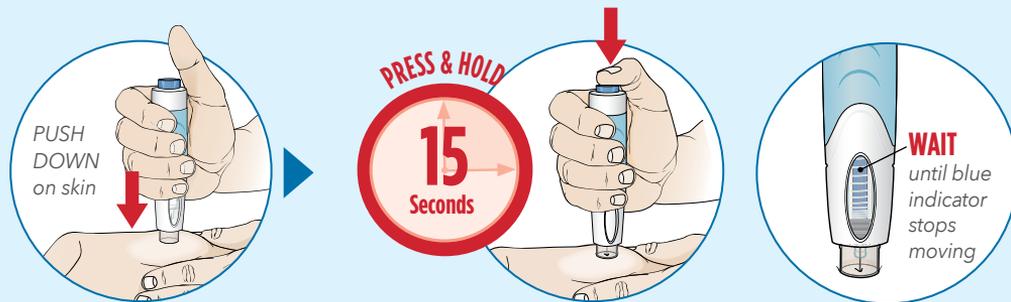
Pinch your skin

Position the Autoinjector so you can see the viewing window. Make sure it is at a 90° angle to the injection site. With your other hand, gently pinch the cleaned skin.



Inject your dose

Complete all steps to deliver your full dose of medicine:



Push down

Push down on the skin to unlock the Autoinjector.

Press button

Press button and hold for 15 seconds. You will hear a click as the injection begins.

Watch window

Watch window and wait until blue indicator stops moving in window.

Remove the Autoinjector from the injection site by lifting it straight up. After you remove it from your skin, the transparent tip will lock over the needle. Release the pinched skin.

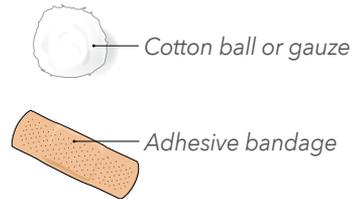
Step 4: After the injection

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.

- DO NOT rub the injection site

If needed, you may cover the injection site with an adhesive bandage.



Dispose of your used ClickJect™ Autoinjector after injection:

- Put your used ClickJect™ Autoinjector in an FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles or 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
 - Equipped with a tight-fitting, puncture-resistant lid without sharps being able to come out
 - Upright and stable during use
 - Leak resistant
 - 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 it. 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 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 handle the Autoinjector carefully to prevent accidental needle stick injury and possibly spreading infection. **Keep the Autoinjector and the disposal container out of the reach of children.**

Frequently Asked Questions

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

A. This step is primarily for your comfort. If the medicine is cold, the injection may take longer than 15 seconds. Never try to speed the warming process in any way, like using the microwave or placing the Autoinjector in warm water.

Q. What if I accidentally remove the needle cover (orange cap) before I'm ready to use the Autoinjector?

A. If you remove the cover before you are ready to use the Autoinjector, be careful. Do not try to replace it. Use the Autoinjector as soon as possible. While you prepare for the injection, carefully place the Autoinjector on its side on a clean, flat surface. Be sure to keep the Autoinjector away from children.

Q. What if the Autoinjector appears to be broken or damaged?

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

Q. What if the injection was not triggered?

A. Before the injection can be triggered, the device must be unlocked. To unlock, firmly push the Autoinjector down on the skin without touching the button. Once the stop-point is felt, the device is unlocked and can be triggered by pushing the button.

Q. I feel a little bit of burning and/or pain during injection. Is this normal?

A. When giving an injection, you may feel a prick from the needle. Sometimes, the medicine can cause slight irritation near the injection site. If this occurs, the discomfort should be mild to moderate. If you experience any side effects, including pain, swelling, or discoloration near the injection site, contact your healthcare provider or pharmacist immediately. You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Q. How do I know I received my full dose?

A. Before lifting the Autoinjector from the injection site, check to ensure that the blue indicator has stopped moving. Then, before disposing of the Autoinjector, check the bottom of the transparent viewing window to make sure there is no liquid left inside. If the medicine has not been completely injected, consult your healthcare provider or pharmacist.

Frequently Asked Questions

Q. How should I dispose of a used Autoinjector?

A. Place the used Autoinjector into an FDA-cleared sharps disposal container right away after use.

- 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 it. There may be state or local laws about how you should throw away used needles and Autoinjectors. 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>
- Do not recycle your used sharps disposal container

Q. How should I keep my Autoinjector cool while traveling?

A. Your healthcare provider or pharmacist may be familiar with special carrying cases for injectable medicines. Store at 36°F to 46°F (2°C to 8°C). Do not freeze. Protect from light.

Q. Can I take my Autoinjector on board an aircraft?

A. Generally, this is allowed. Be sure to pack your Autoinjector in your carry-on, and do not put it in your checked luggage. You should carry it with you in your travel cooler at a temperature of 36°F to 46°F (2°C to 8°C) until you are ready to use it. Airport security procedures and airline policies change from time to time, so it's best to check with airport authorities and the airline for any special rules. Prior to flying, get a letter from your healthcare provider to explain that you are traveling with prescription medicine that uses a device with a needle; if you are carrying a sharps container in your carry-on baggage, notify the screener at the airport.

**Q. What if my Autoinjector does not stay cool for an extended period of time?
Is it dangerous to use?**

A. Contact 1-800-673-6242 for details.

Important:

If you have questions or concerns about your Autoinjector, please contact a healthcare provider familiar with ORENCIA 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.

Diabetes: If you have diabetes and use a blood glucose monitor to check your sugar levels.

- The **infusion** of ORENCIA 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

Please see additional Important Safety Information on the next page.

Important Safety Information (cont.)

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.

If you are **Taking Other Biologic Medicines to Treat RA** 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 with other biologic medicines that may affect your immune system.

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 with other biologic medicines that may affect your immune system.

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.

Please see additional Important Safety Information on the next page.

Important Safety Information (cont.)

- **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.
- **Respiratory problems in people with COPD.** You may get certain respiratory problems more often if you receive ORENCIA 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® (abatacept) 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 not approved for pediatric PsA.
- Pediatric PsA 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 read the Patient Information in the Full Prescribing Information [here](#).

Summary of side effects for first-use safety integration

ORENCIA® (abatacept) SELECTED IMPORTANT SAFETY INFORMATION FOR PATIENTS

ORENCIA can cause serious side effects, including serious infections, allergic reactions, hepatitis B infection in carriers of the virus, interactions with vaccines, respiratory problems with COPD, and cancer. Side effects of ORENCIA, which are considered common, include: headache, upper respiratory tract infection, sore throat and nausea. Other side effects in children and adolescents may include diarrhea, cough, fever, and abdominal pain. This is not a complete list of all side effects with ORENCIA. Tell your healthcare provider if you have any side effects while taking ORENCIA.

Please read more information about potential side effects with ORENCIA [here](#).

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](https://www.orencia.com) or call **1-800-ORENCIA (1-800-673-6242)**.

Please read the [Patient Information here](#).

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

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427-US-2300140 11/23

 **ORENCIA**[®]
(abatacept)
Injection for Intravenous Use
Injection for Subcutaneous Use