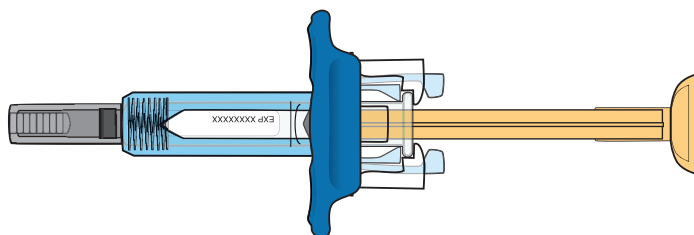


Instructions for Use
ORENCIA® (oh-REN-see-ah)
(abatacept)
Prefilled syringe with BD UltraSafe Passive™ needle guard

ORENCIA® prefilled syringe with
BD UltraSafe Passive™ needle guard
(abatacept) injection



Read these instructions before you start using your ORENCIA prefilled syringe and 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.

Important:

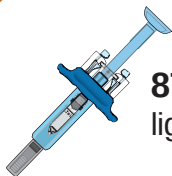
- **Keep the prefilled syringe in the refrigerator** until ready to use.
- **Do not freeze.**

Before you begin: get to know your prefilled syringe

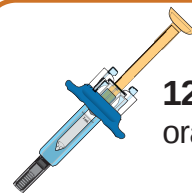
There are **3 types** of prefilled syringes:



50 mg/0.4 mL:
white plunger

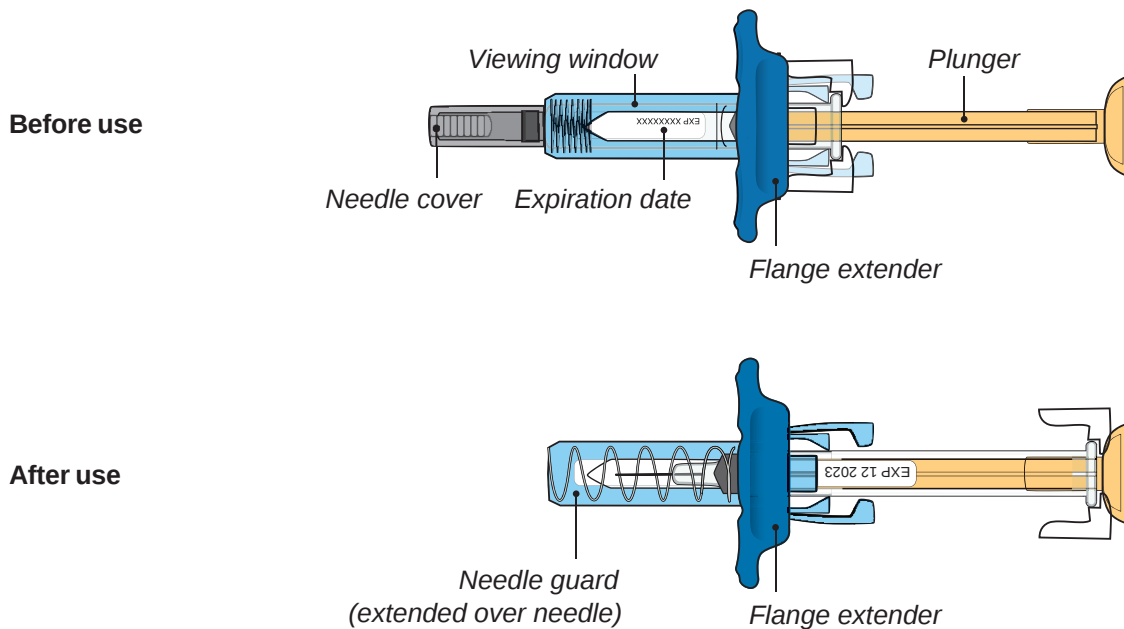


87.5 mg/0.7 mL:
light blue plunger



125 mg/mL:
orange plunger

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

- **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.

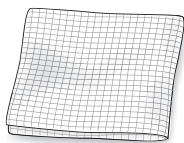
Go to Step 1

Step 1: Preparing for an ORENCIA injection

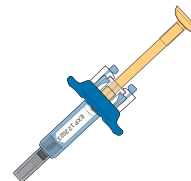
Gather and place supplies for your injection on a clean, flat surface.

Only the prefilled syringe is included in the package:

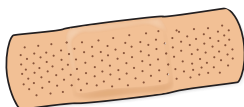
Alcohol swab



Prefilled syringe with
UltraSafe Passive
needle guard



Adhesive bandage



Sharps disposal container



Cotton ball or gauze



Let your prefilled syringe warm up.

Remove 1 prefilled syringe from the refrigerator and wait **30 minutes** to allow it to reach room temperature.

- **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.

Wait



Wash your hands well with soap and water.

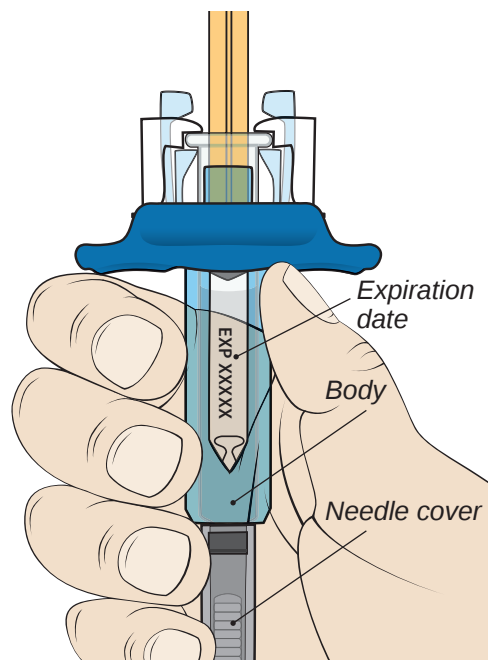
Go to Step 2



Step 2: Examine the 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.

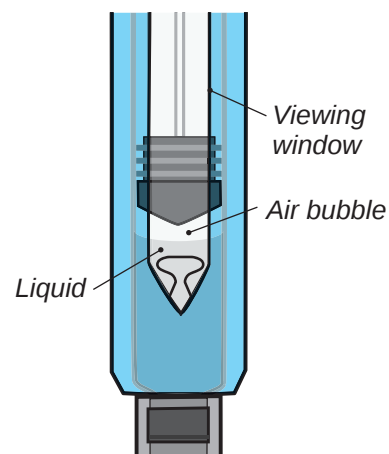


Check the Liquid.

- **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.**

Note: the 50 mg prefilled syringe is shown.

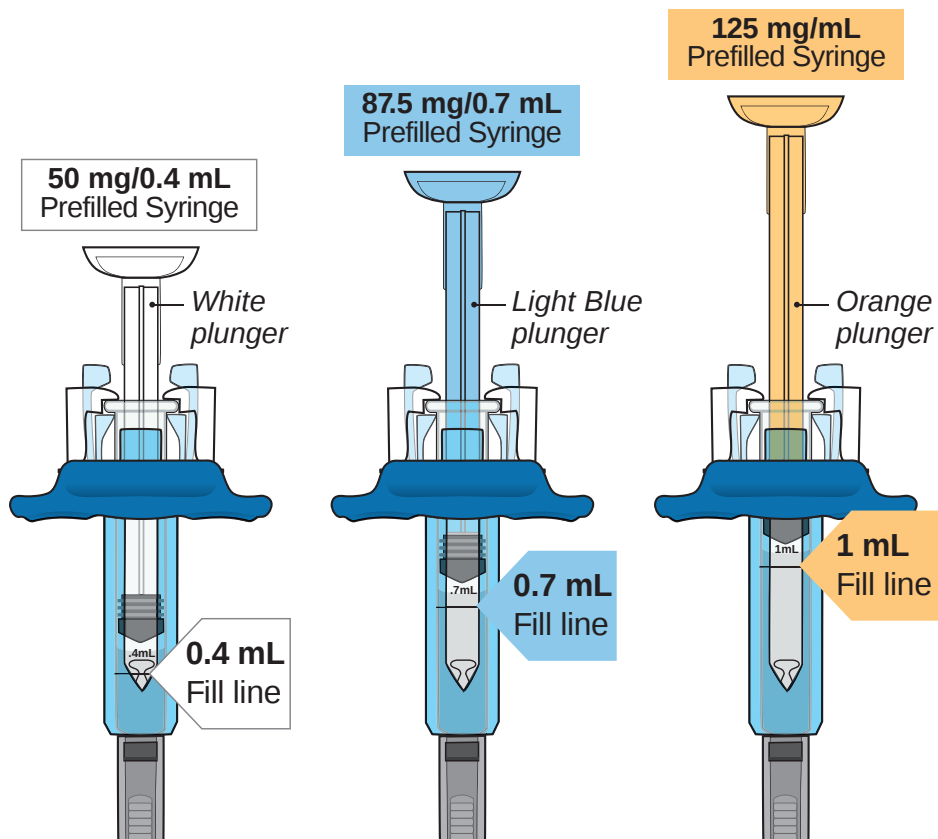
Note: It is normal to see an air bubble. **Do not** attempt to remove it.



Go to Step 3

Step 3: Check the dose on the 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:



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

Go to Step 4

Step 4: Choose and prepare an injection site

Choose your injection site.

Choose your injection site in either the stomach (**abdomen**), front of the **thighs**, or outer area of **upper arm** (only if caregiver administered).

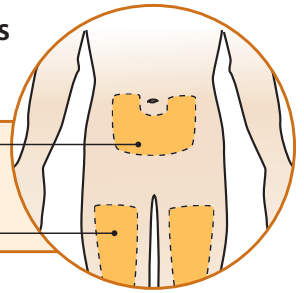
Rotate injection site.

- 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

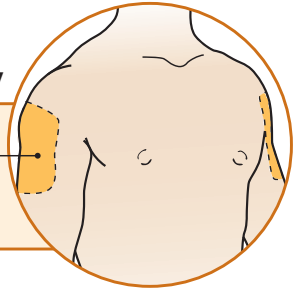
*Abdomen,
avoid 2 inches
around navel*

Front of thighs



Caregiver Only

*Outer area of
upper arms*



Gently clean 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.

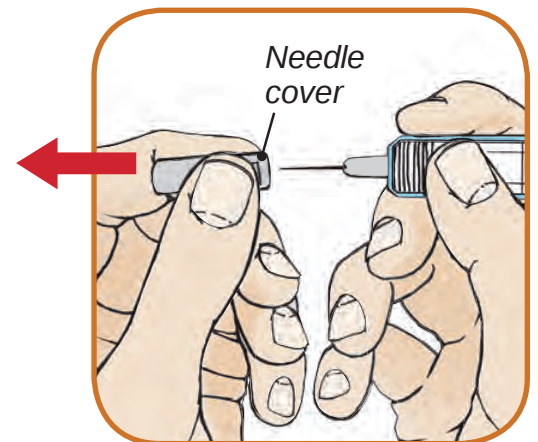
Remove the needle cover by holding the body of the prefilled syringe with one hand and pulling the cover straight off with your other hand.

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.

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

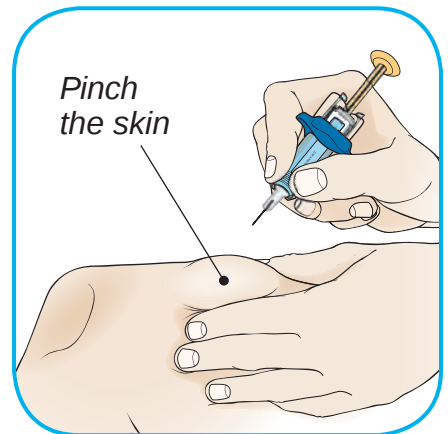
- **Do not recap** the prefilled syringe, as this may damage the needle.



Go to Step 5

Step 5: Inject Your Dose of ORENCIA

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**.

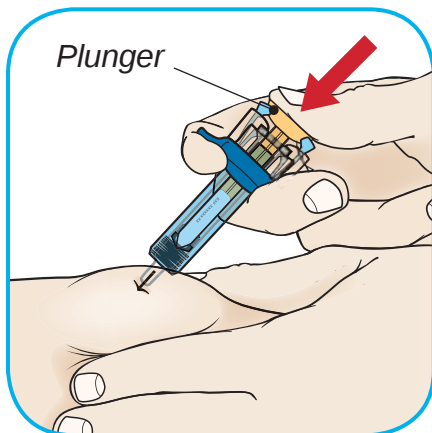


Insert the needle.

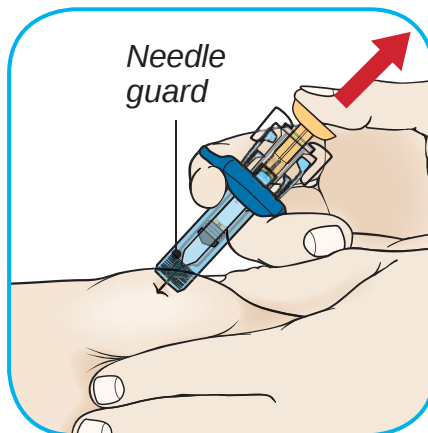
Gently insert the needle into the pinched skin at a 45° angle.



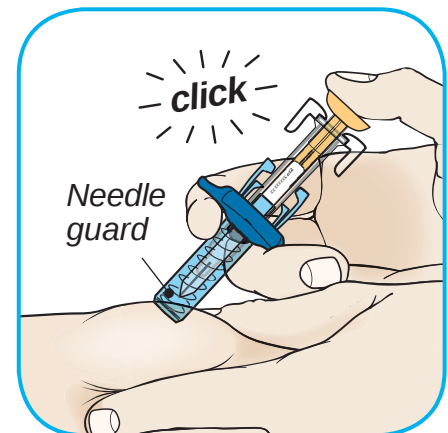
Complete all steps to deliver your full dose of the medicine.



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



Release the 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.

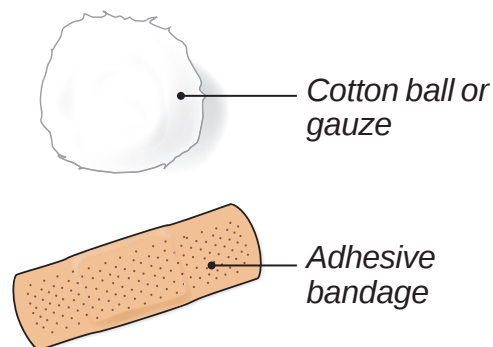
Remove the prefilled syringe and let go of the pinched skin.

Go to Step 6

Step 6: After the injection

Care of 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.



Throwing away (disposing of) used prefilled syringes:

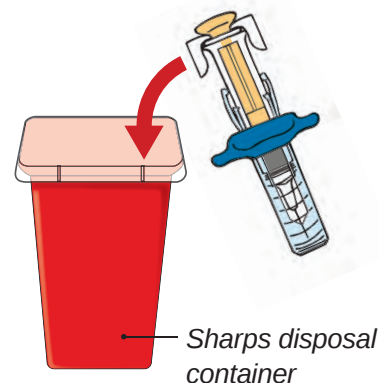
- Put your used ORENCIA prefilled syringes in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose needles and prefilled syringes in your household trash.**
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic,
 - can be closed 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 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>.
- **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.

Go to next page

See **Frequently Asked Questions** for additional throwing away (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 the ORENCIA prefilled syringes and the sharps disposal container out of the reach of children.



How to store ORENCIA prefilled syringe

- Store ORENCIA in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Keep ORENCIA in the original package and out of the light.
- **Do not** freeze ORENCIA.
- Safely throw away medicine that is out of date or no longer needed.

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.

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,
- can be closed 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>.

Frequently Asked Questions (Continued)

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 1-800-673-6242 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 1-800-673-6242.

Bristol-Myers Squibb Company
Princeton, NJ 08543 USA, U.S. License Number 1713

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

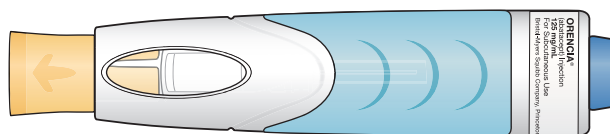
ORENCIA is a registered trademark of Bristol-Myers Squibb Company.

BD UltraSafe Passive™ is a trademark of Becton, Dickinson, and Company.

Revised 10/2023

**Instructions for Use
ORENCIA® ClickJect™ (oh-REN-see-ah)
(abatacept)
Prefilled autoinjector**

**ORENCIA® ClickJect™
(abatacept) injection
Prefilled autoinjector**



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

Read these instructions before you use the ClickJect autoinjector and 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.

Important:

- **Keep the ClickJect autoinjector in the refrigerator** until ready to use.
- **Do not freeze.**

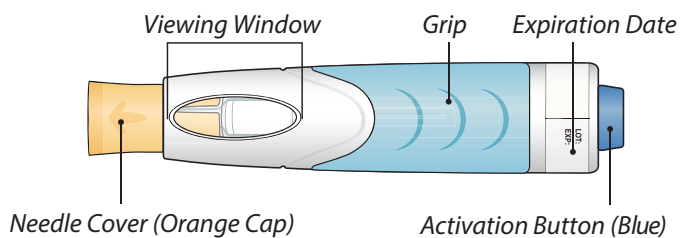
Go to next page

Before you begin:

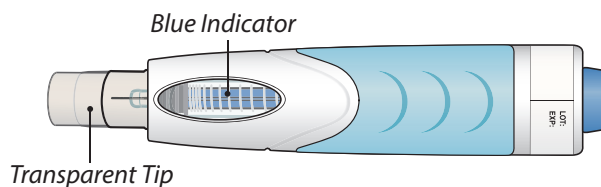
Get to know the ClickJect autoinjector

- The autoinjector automatically delivers the medicine. The transparent tip locks over the needle when the injection is complete and the autoinjector is removed from the skin.
- **Do not remove the orange needle cover until you are ready to inject.**

Before use



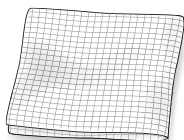
After use



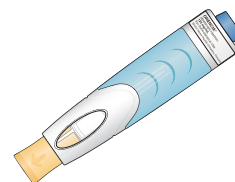
Gather supplies for your injection on a clean, flat surface

(only the ClickJect autoinjector is included in the package):

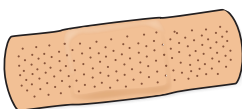
Alcohol swab



ClickJect autoinjector



Adhesive bandage



Sharps disposal container



Cotton ball or gauze



Go to Step 1

Step 1: Prepare your autoinjector

Let your ClickJect autoinjector warm up.

Remove 1 autoinjector from the refrigerator and let it rest at room temperature for **30 minutes**.

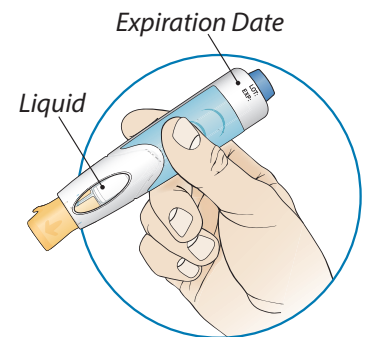
Do not remove the autoinjector needle cover while allowing it to reach room temperature.

Wash your hands well with soap and water.

Examine the ClickJect 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. You may see a small air bubble. You do not need to remove it. **Do not inject** if the liquid is cloudy, discolored, or has particles in it.

Go to Step 2



Step 2: Prepare for injection

Choose your injection site in either the stomach (**abdomen**), front of the **thighs**, or outer area of **upper arm** (only if caregiver administered).

Rotate 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 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.

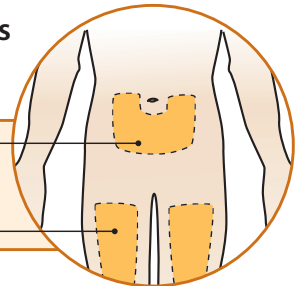
Note: It is normal to see a drop of fluid leaving the needle.

Go to Step 3

Injection Areas Self-Injection and Caregiver

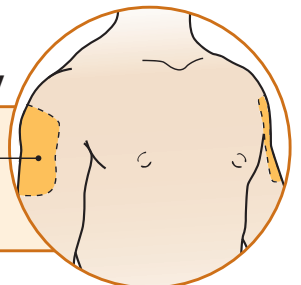
*Abdomen, —
avoid 2 inches
around navel*

Front of thighs

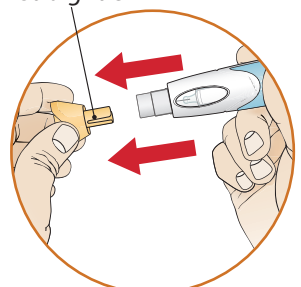


Caregiver Only

*Outer area of
upper arms*

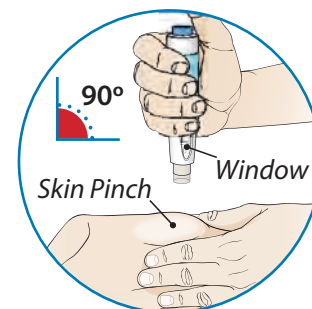


*Pull
Needle Cover
Straight Off*

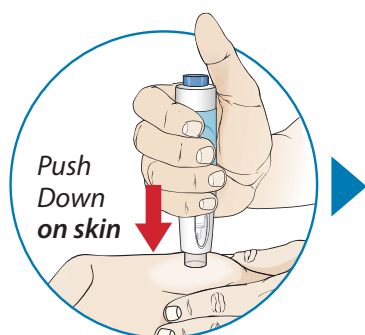


Step 3: Inject your dose

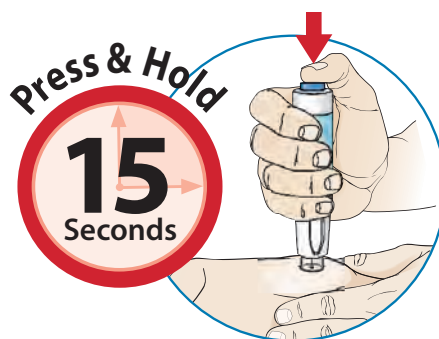
Position the autoinjector so you can see the **viewing window** and it is at a 90° angle to the injection site. With your other hand, gently **pinch the cleaned skin**.



Complete all steps to deliver your full dose of medicine:

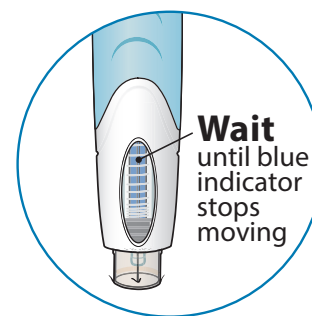


Push down on the skin to unlock the autoinjector.



Press button, hold for 15 seconds and watch the window.

- You will hear a click as the injection begins.
- To deliver the full dose of medicine, hold the autoinjector in place for 15 seconds **and** wait until the blue indicator stops moving in the window.



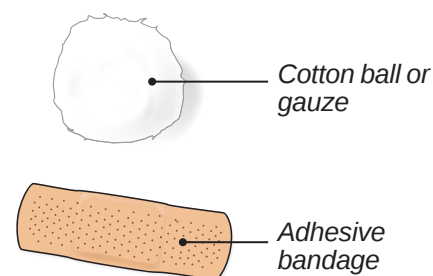
Remove the ClickJect autoinjector from the injection site by lifting it straight up. After you remove it from your skin, the transparent tip will lock over the needle. Release the pinched skin.

Go to Step 4

Step 4: After the Injection

Care of 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.



Go to next page

Throwing away (disposing of) used ClickJect autoinjectors:

- Put your used ClickJect autoinjector in a 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 a FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic,
 - can be closed 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 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>.
- **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.

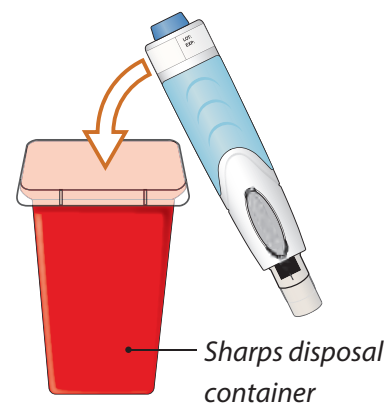
See **Frequently Asked Questions** for additional throwing away (disposal) information.

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 autoinjector and the sharps disposal container out of the reach of children.

How to store ORENCIA ClickJect autoinjector

- Store ORENCIA in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Keep ORENCIA in the original package and out of the light.
- **Do not** freeze ORENCIA.
- Safely throw away medicine that is out of date or no longer needed.



Go to next page

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. When 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 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 make sure that the blue indicator has stopped moving. Then, before throwing away (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.

Q. How should I throw away (dispose of) a used autoinjector?

A. Place 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,
 - can be closed 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 throw away (dispose of) your sharps disposal container. 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.

Frequently Asked Questions (Continued)

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 in the refrigerator 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.

If you have questions or concerns about your autoinjector, please contact a healthcare provider or call our toll-free help line at 1-800-673-6242.

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Revised 1/2024

427-US-2400020 01/24

