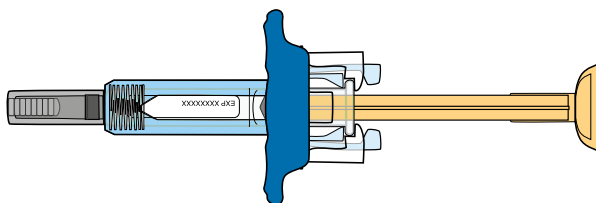


INSTRUCTIONS FOR USE

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.**

Indication/Usage

Adult Rheumatoid Arthritis (RA):

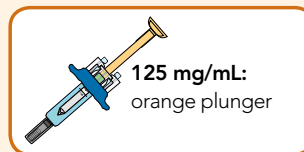
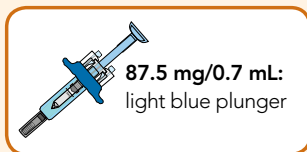
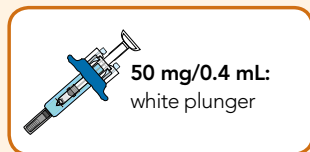
ORENCIA® (abatacept) is a prescription medicine that reduces signs and symptoms in adults with moderate to severe RA, including those who have not been helped enough by other medicines for RA. ORENCIA may prevent further damage to your bones and joints and may help your ability to perform daily activities. In adults, ORENCIA may be used alone or with other RA treatments other than tumor necrosis factor (TNF) antagonists.

Juvenile Idiopathic Arthritis (JIA): 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.

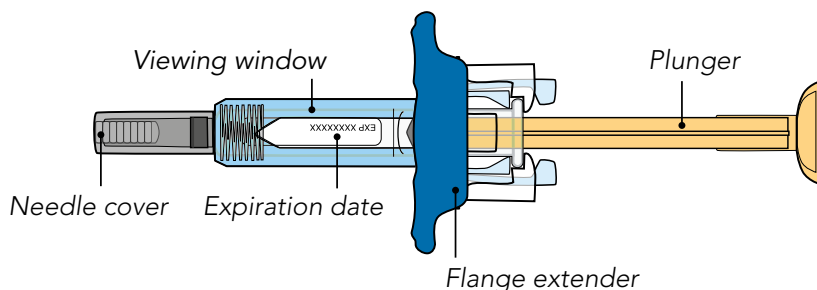
Before You Begin: Get to Know Your Prefilled Syringe

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

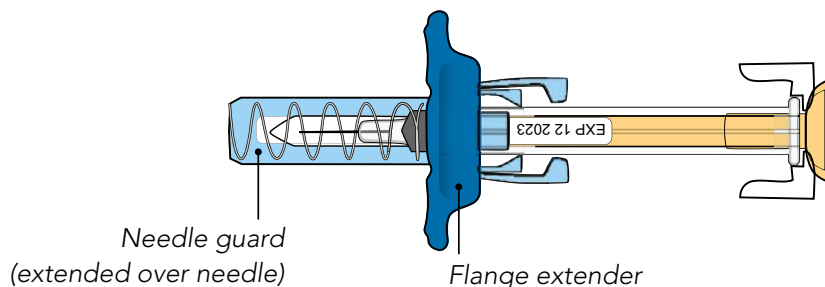


The type of prefilled syringe you receive depends on the dose prescribed by your healthcare provider. The 125 mg/mL prefilled syringe is shown below.

Before Use



After Use



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® (abatacept) Injection

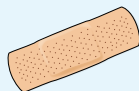
Gather and place supplies for your injection on a clean, flat surface.

Only the prefilled syringe is included in the package:

- Alcohol swab



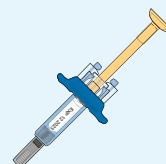
- Adhesive bandage



- Cotton ball or gauze



- Prefilled Syringe with UltraSafe Passive Needle Guard



- Sharps disposal container



Let your Prefilled Syringe warm up.

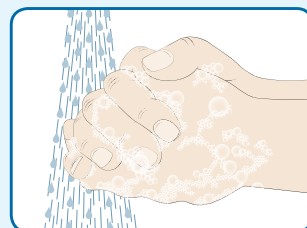
Remove one prefilled syringe from the refrigerator and wait **30 minutes** to allow it to reach room temperature.

- **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



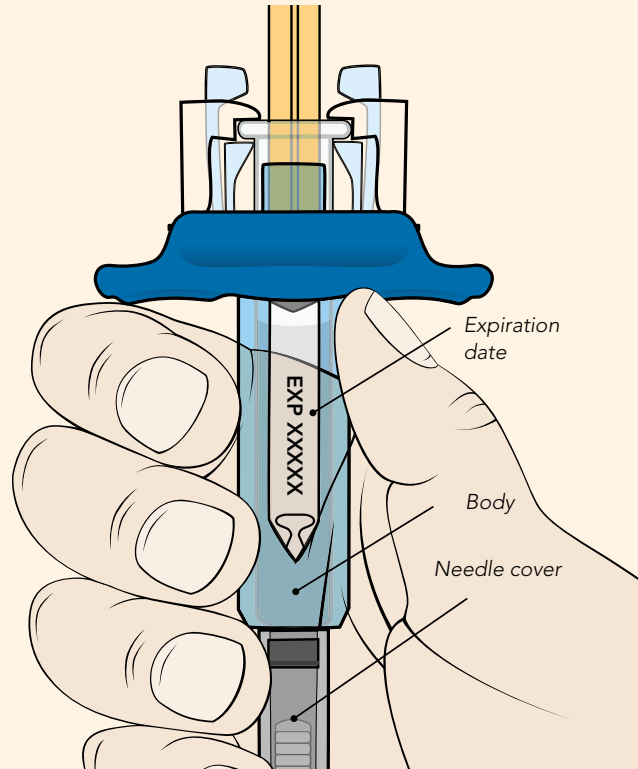
Wash your hands well with soap and water.



Step 2: Examine the Prefilled Syringe

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

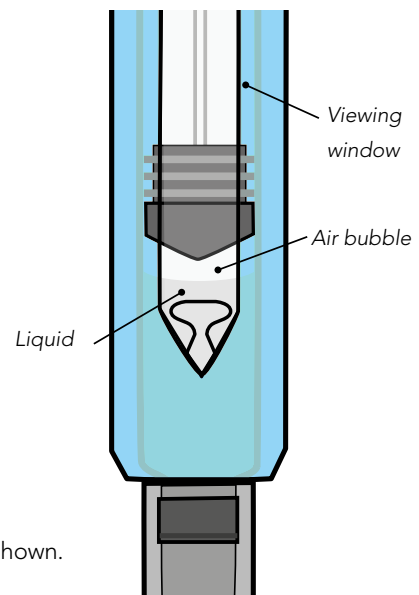
- **Check the expiration date** printed on the label
Do not use if the expiration date has passed.
- **Check the prefilled syringe for damage.**
Do not use if it is cracked or broken.



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.**

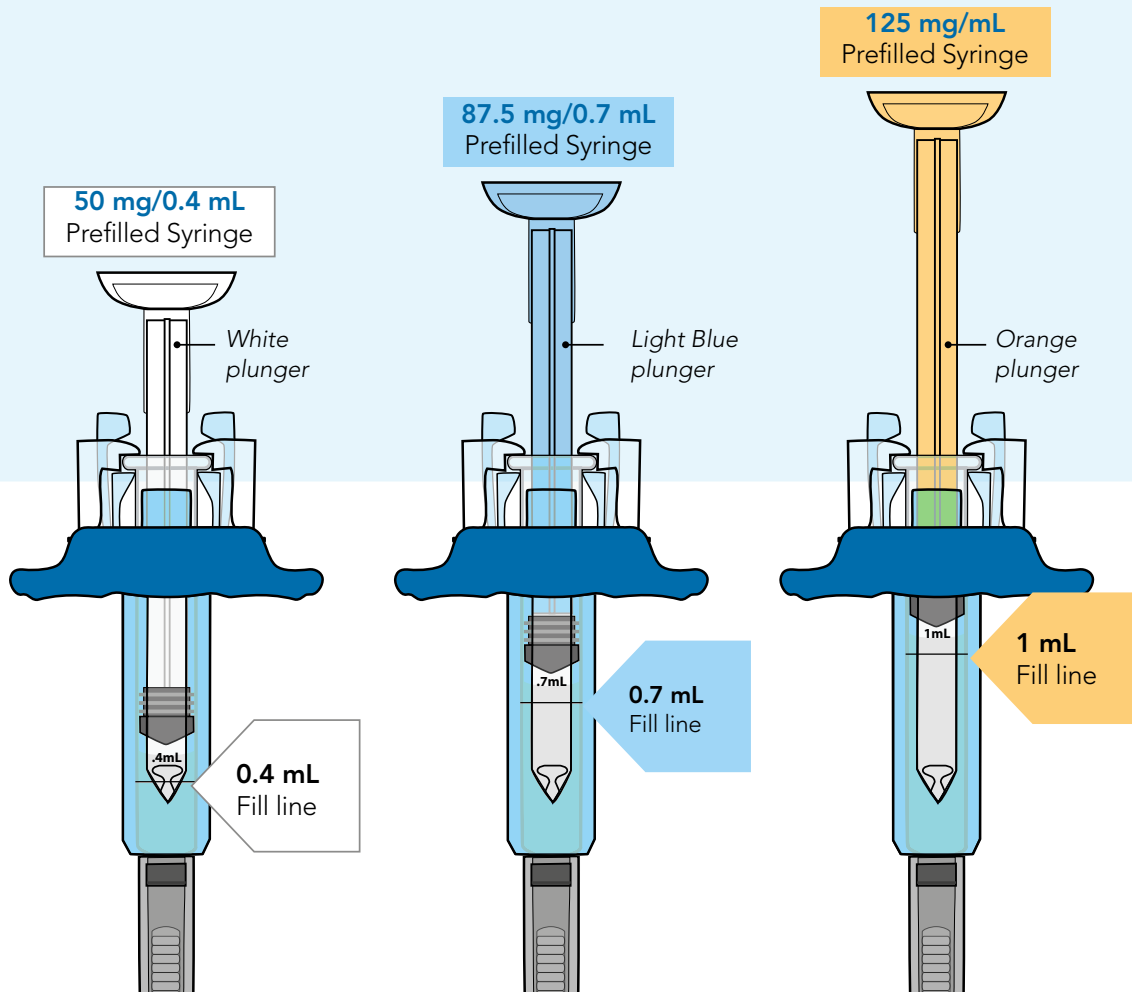


*Note: the 50 mg prefilled syringe is shown.

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

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.

Step 4: Choose and Prepare an Injection Site

Choose your injection site.

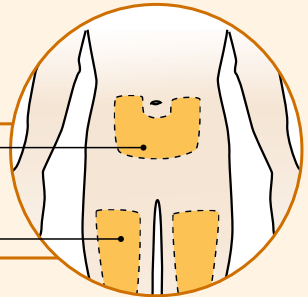
Choose your injection site in either the stomach (**abdomen**), front of the **thighs**, or outer area of **upper arm** (only if caregiver administered).

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.

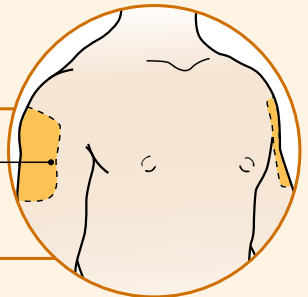
Injection Areas Self-Injection and Caregiver

Abdomen,
avoid 2 inches
around navel
Front of thighs



Caregiver ONLY

Outer area of
upper arms



Gently clean injection site.

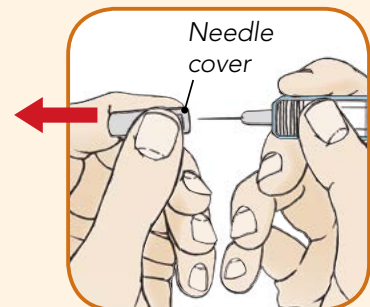
- Wipe the injection site with an alcohol swab and let it air dry.
- **Do not** touch the injection site again before giving the injection.
- **Do not** fan or blow on the clean area.


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.

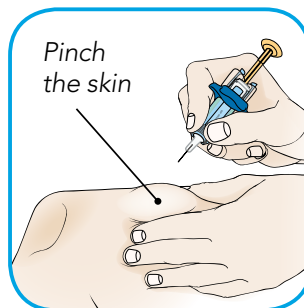


 **DO NOT RECAP** the prefilled syringe, as this may damage the needle.

Go to Step 5 ►

Step 5: Inject Your Dose of ORENCIA® (abatacept)

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**.

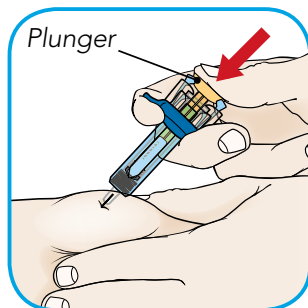


Insert the needle.

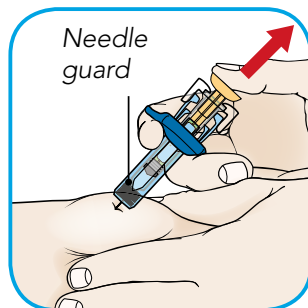
Gently insert the needle into the pinched skin at a 45° angle.



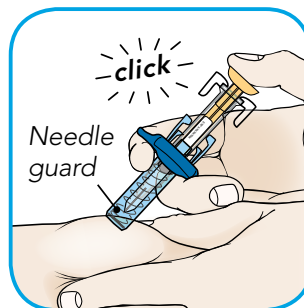
Complete all steps to deliver your full dose of the medicine.



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



Release 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

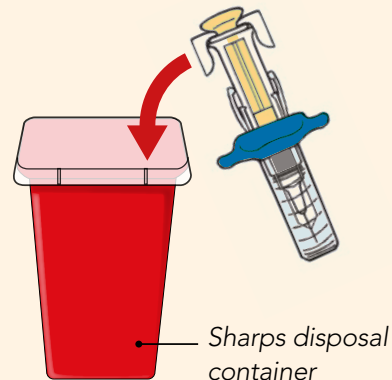
Care of injection site:

- 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.



Disposing of used Prefilled Syringes:

- Put your used ORENCIA® (abatacept) 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,
 - 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.



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.

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.

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,
- 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>.

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.

Important Safety Information for ORENCIA® (abatacept)

Inform your healthcare provider of the following, before you receive treatment with ORENCIA:

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® (abatacept), 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.

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.

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** 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.

Please see additional Important Safety Information on the next page.

Go to Next Page ►

Important Safety Information for ORENCIA® (abatacept) (cont.)

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. ORENCIA may cause some vaccinations to be less effective.
- **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.

Please [click here](#) to read the Patient Information in the Full Prescribing Information.

**If you have questions or concerns about
your ORENCIA® (abatacept) Prefilled Syringe
with BD UltraSafe Passive™ Needle Guard, please
contact a healthcare provider familiar with
ORENCIA or call our toll-free help line at
1-800-ORENCIA (1-800-673-6242).**

Please [click here](#) to read the Patient Information in the Full Prescribing Information.



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