INSTRUCTIONS FOR USE

ORENCIA® ClickJect™ (abatacept) Injection
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.

Indication/Usage

Adult Rheumatoid Arthritis (RA): ORENCIA® (abatacept) is a prescription medicine that reduces signs and symptoms in adults 18 years or older 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.

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.

Please read Important Safety Information on pages 16-18.
Before You Begin

Get to know the ClickJect Autoinjector

• 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.

• **Do not remove the orange needle cover until you are ready to inject.**
Gather supplies for your injection on a clean, flat surface (only the ClickJect Autoinjector is included in the package):

- Alcohol swab
- Adhesive bandage
- Cotton ball or gauze
- ClickJect Autoinjector
- Sharps disposal container
Let your ClickJect Autoinjector warm up.

Remove one 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.
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. **Do not inject** if the liquid is cloudy, discolored, or has particles in it.

Wash your hands well with soap and water.
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 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**

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 skin**
- **PRESS & HOLD** for 15 Seconds
- **WAIT** until blue indicator stops moving
Press button, HOLD for 15 seconds AND watch 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 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 skin pinch.
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.

Disposing of used ClickJect Autoinjectors:
• Put your used ClickJect Autoinjector 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 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 Autoinjector and the 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.
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.
Q. How should I 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 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.

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.

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.
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, 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.

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.

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.

*Please see additional Important Safety Information on the next page.*
Important Safety Information for ORENCIA® (abatacept) (cont.)

• **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 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.

*Click here for the Patient Information in the Full Prescribing Information.*
If you have questions or concerns about your ORENCIA® (abatacept) ClickJect™ Autoinjector, please contact a healthcare provider familiar with ORENCIA or call our toll-free help line at 1-800-ORENCIA (1-800-673-6242).

Click here for the Patient Information in the Full Prescribing Information.