

PATIENT INFORMATION

ORENCIA[®] (oh-REN-see-ah)
(abatacept)

Lyophilized Powder for Intravenous Infusion

ORENCIA[®] (oh-REN-see-ah)
(abatacept)

Injection, Solution for Subcutaneous Administration

Read this Patient Information before you start using ORENCIA and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is ORENCIA?

ORENCIA is a prescription medicine that reduces signs and symptoms in:

- adults with moderate to severe rheumatoid arthritis (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.
- children and adolescents 6 years of age and older with moderate to severe polyarticular juvenile idiopathic arthritis (JIA). ORENCIA may be used alone or with methotrexate.

It is not known if ORENCIA is safe and effective in children under 6 years of age.

It is not known if ORENCIA is safe and effective in children for uses other than juvenile idiopathic arthritis.

What should I tell my healthcare provider before using ORENCIA?

Before you use ORENCIA, tell your healthcare provider if you:

- have any kind of infection even if it is small (such as an open cut or sore), or an infection that is in your whole body (such as the flu). If you have an infection when taking ORENCIA, you may have a higher chance for getting serious side effects.
- have an infection that will not go away or an infection that keeps coming back.
- are allergic to abatacept or any of the ingredients in ORENCIA. See the end of this leaflet for a list of the ingredients in ORENCIA.

- have or have had inflammation of your liver due to an infection (viral hepatitis). Before you use ORENCIA, your healthcare provider may examine you for hepatitis.
- have had a lung infection called tuberculosis (TB), a positive skin test for TB, or you recently have been in close contact with someone who has had TB. Before you use ORENCIA, your healthcare provider may examine you for TB or perform a skin test. Symptoms of TB may include:
 - a cough that does not go away
 - weight loss
 - fever
 - night sweats
- are scheduled to have surgery.
- recently received a vaccination or are scheduled for a vaccination. If you are receiving ORENCIA, and for 3 months after you stop receiving ORENCIA, you should not receive live vaccines.
- have a history of a breathing problem called chronic obstructive pulmonary disease (COPD).
- have diabetes and use a blood glucose monitor to check your blood sugar (blood glucose) levels. ORENCIA for intravenous infusion (given through a needle placed in a vein) contains maltose, a type of sugar that can give false high blood sugar readings with certain types of blood glucose monitors, on the day of ORENCIA infusion. Your doctor may tell you to use a different way to monitor your blood sugar levels.
- ORENCIA for subcutaneous injection (injected under the skin) does not contain maltose. You do not need to change your blood sugar monitoring if you are taking ORENCIA subcutaneously.
- have any other medical conditions.
- are pregnant or planning to become pregnant. It is not known if ORENCIA can harm your unborn baby.

Bristol-Myers Squibb Company has 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 doctors to contact the registry for them by calling 1-877-311-8972.
- are breast-feeding or plan to breast-feed. It is not known if ORENCIA passes into your breast milk. You and your healthcare provider should decide if you will use ORENCIA or breast-feed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

ORENCIA may affect the way other medicines work, and other medicines may affect the way ORENCIA works causing serious side effects.

Especially tell your healthcare provider if you take other biologic medicines to treat RA or JIA that may affect your immune system, such as:

- Enbrel® (etanercept)
- Humira® (adalimumab)
- Remicade® (infliximab)
- Kineret® (anakinra)
- Rituxan® (rituximab)
- Simponi® (golimumab)
- Cimzia® (certolizumab pegol)
- Actemra® (tocilizumab)

You may have a higher chance of getting a serious infection if you take ORENCIA with other biologic medicines for your RA or JIA.

Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new prescription.

How should I use ORENCIA?

- You may receive ORENCIA given by a healthcare provider through a vein in your arm (IV or intravenous infusion). It takes about 30 minutes to give you the full dose of medicine. You will then receive ORENCIA 2 weeks and 4 weeks after the first dose and then every 4 weeks.
- You may also receive ORENCIA as an injection under your skin (subcutaneous). If your healthcare provider decides that you or a caregiver can give your injections of ORENCIA at home, you or your caregiver should receive training on the right way to prepare and inject ORENCIA. Do not try to inject ORENCIA until you have been shown the right way to give the injections by your healthcare provider.
- Your healthcare provider will tell you how much ORENCIA to use and when to use it.
- **See the Instructions for Use at the end of this Patient Information leaflet for instructions about the right way to prepare and give your ORENCIA injections at home.**

What are the possible side effects of ORENCIA?

ORENCIA can cause serious side effects including:

- **infections.** ORENCIA can make you more likely to get infections or make the infection that you have get worse. Call your healthcare provider right away if you have any symptoms of an infection. Symptoms of an infection may include:
 - fever

- feel very tired
 - have a cough
 - have flu-like symptoms
 - warm, red, or painful skin
- **allergic reactions.** Allergic reactions can happen to people who use ORENCIA. Call your healthcare provider or go to the emergency room right away if you have any symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
 - hives
 - swollen face, eyelids, lips, or tongue
 - trouble breathing
 - **hepatitis B infection** in people who carry the virus in their blood. 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 while you use ORENCIA.
 - **vaccinations.** You should not receive ORENCIA with certain types of vaccines (live vaccines). ORENCIA may also cause some vaccinations to be less effective. Talk with your healthcare provider about your vaccination plans.
 - **breathing problems in patients with Chronic Obstructive Pulmonary Disease (COPD).** Some people may get certain respiratory problems more often if you receive ORENCIA and have COPD. Symptoms of respiratory problems include:
 - COPD that becomes worse
 - cough
 - trouble breathing
 - **cancer (malignancies).** Certain kinds of cancer have been reported in people using ORENCIA. It is not known if ORENCIA increases your chance of getting certain kinds of cancer.

Common side effects of ORENCIA include:

- headache
- upper respiratory tract infection
- sore throat
- nausea

In children and adolescents, other side effects may include:

- diarrhea
- cough
- fever
- abdominal pain

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of ORENCIA. For more information, ask your healthcare provider or pharmacist.

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

How should I store ORENCIA?

- 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.

Keep ORENCIA and all medicines out of the reach of children.

General information about the safe and effective use of ORENCIA

Medicines are sometimes prescribed for purposes other than those listed in this Patient Information leaflet. Do not use ORENCIA for a condition for which it was not prescribed. Do not give ORENCIA to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about ORENCIA. If you would like more information, talk to your healthcare provider.

You can ask your pharmacist or healthcare provider for information about ORENCIA that is written for health professionals.

For more information, go to www.ORENCIA.com or call 1-800-ORENCIA.

What are the ingredients in ORENCIA?

Active ingredient: abatacept

Intravenous inactive ingredients: maltose, monobasic sodium phosphate, sodium chloride for administration

Subcutaneous inactive ingredients: sucrose, poloxamer 188, monobasic sodium phosphate monohydrate, dibasic sodium phosphate anhydrous, water for injection

This Patient Information has been approved by the U.S. Food and Drug Administration.

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Instructions for Use ORENCIA® (oh-REN-see-ah) (abatacept) Prefilled Syringe

Read and follow these Instructions for Use that come with your ORENCIA prefilled syringe before you start using it and each time you get a refill. Before you use ORENCIA prefilled syringe for the first time, make sure your healthcare provider shows you the right way to use it.

Do not remove the needle cover (the cap) until you are ready to inject ORENCIA.

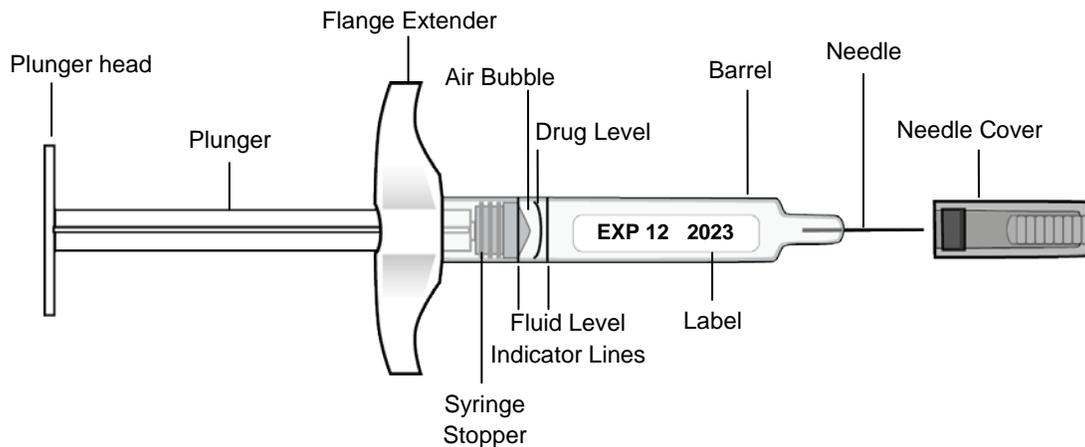


Figure A

- The ORENCIA prefilled syringe has a flange extender that makes it easier to hold the syringe and inject (**see Figure A**).

Supplies needed for your ORENCIA Prefilled Syringe Injection (see Figure B):

- a new ORENCIA prefilled syringe
- alcohol swab
- cotton ball or gauze
- adhesive bandage
- puncture resistant container (sharps container)

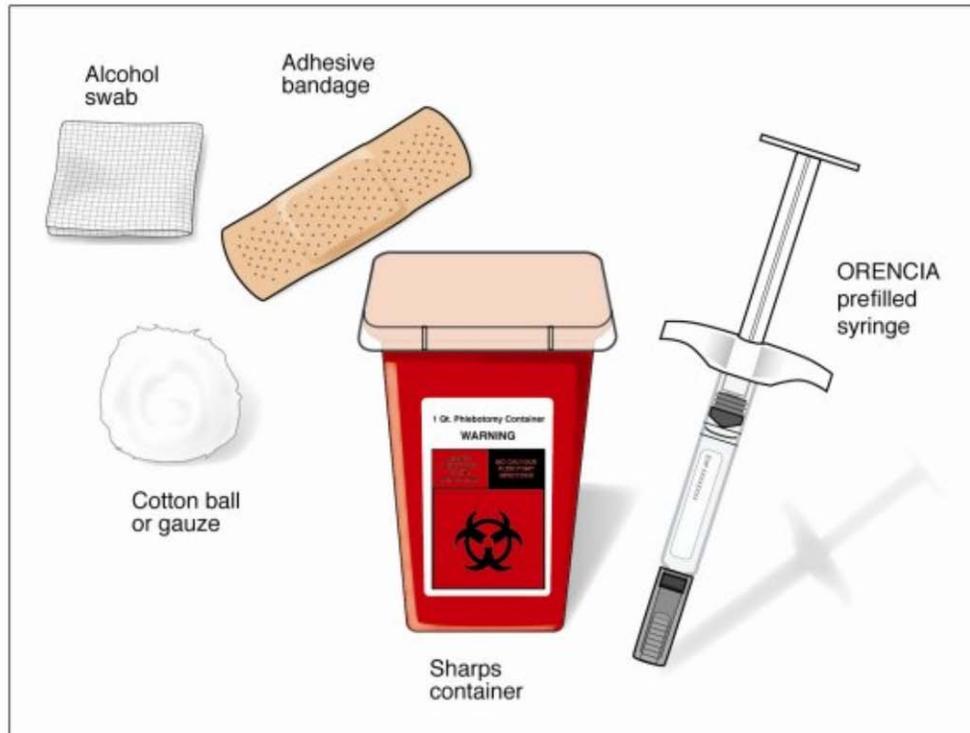


Figure B

STEP 1: Preparing for an ORENCIA Injection

Find a comfortable space with a clean, flat, working surface.

- Check the expiration date on the ORENCIA prefilled syringe (**see Figure A**). **Do not** use it if the expiration date has passed. Throw it away and get a new one.
- Remove 1 single-use ORENCIA prefilled syringe from the refrigerator and let it warm up for 30 to 60 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 ORENCIA prefilled syringe to reach room temperature.

- Keep your unused syringes in their original carton and keep in the refrigerator at 36°F to 46°F (2°C to 8°C). **Do not** freeze.
- Hold your ORENCIA prefilled syringe by the barrel with the covered needle pointing down (**see Figure C**).

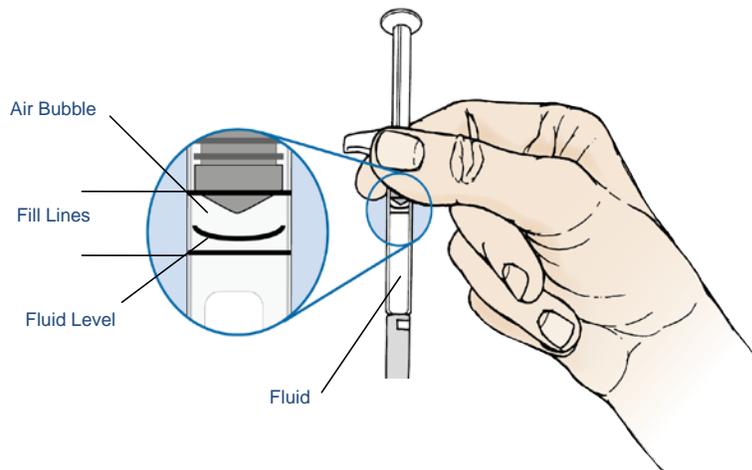


Figure C

- Check the liquid in the ORENCIA prefilled syringe. It should be clear and colorless to pale yellow. **Do not** inject ORENCIA if the liquid is cloudy, discolored, or has lumps or particles in it. Throw the syringe away and get a new one.
- Check that the amount of liquid in your ORENCIA prefilled syringe is the correct amount. The liquid should be between the two lines on the syringe barrel (**see Figure C**).
- **Do not** inject ORENCIA if it does not have the correct amount of liquid. Throw the ORENCIA prefilled syringe away and get a new one. It is normal to see an air bubble. There is no reason to remove it.
- Wash your hands well with soap and water.

STEP 2: Choose and Prepare an Injection Site

Choose an Injection Site

- The front of your thigh is a recommended injection area. You may use your abdomen except for the 2-inch area around your navel (**see Figure D**).
- The outer area of the upper arms may also be used only if the injection is being given by a caregiver. Do not attempt to use the upper arm area by yourself (**see Figure E**).

Rotate Injection Site

- Choose a different injection site for each new injection. You may use the same thigh for weekly injections, as long as each injection is at least 1 inch away from the last area you injected.
- Do not inject into areas where your skin is tender, bruised, red, scaly, or hard. Avoid any areas with scars or stretch marks.

Areas for self-injection and caregiver injection

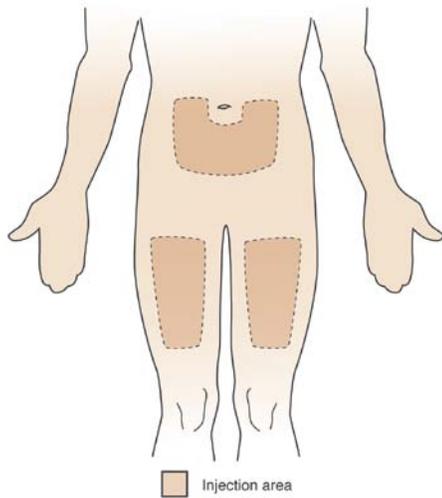


Figure D

Additional injection area for caregivers only

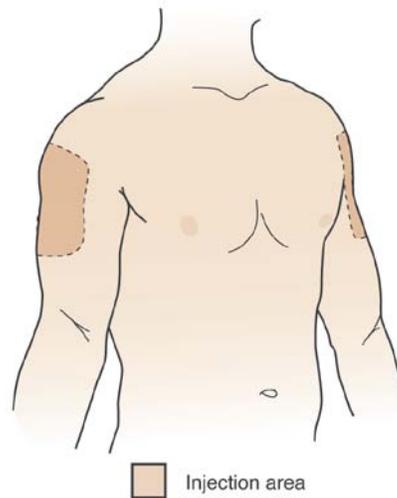


Figure E

Prepare the Injection Site

- Wipe the injection site with an alcohol swab in a circular motion 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.

STEP 3: Inject ORENCIA

- Hold the barrel of the ORENCIA prefilled syringe with one hand and pull the needle cover straight off with your other hand (see Figure F). **Do not** touch the plunger while you remove the needle cover.

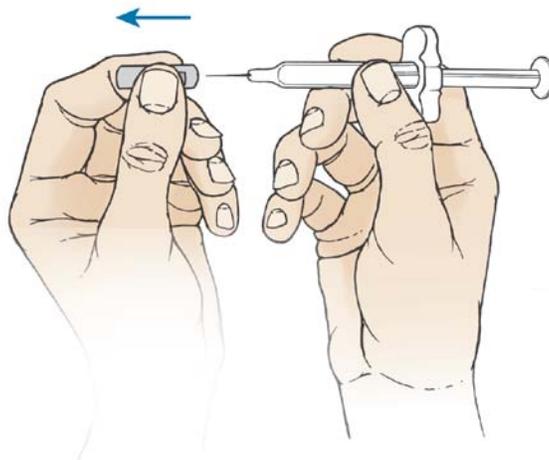


Figure F

- Throw away the needle cover in your household trash.
- There may be a small air bubble in the ORENCIA prefilled syringe barrel. You do not need to remove it.
- You may notice a drop of fluid leaving the needle. This is normal and will not affect your dose.
- **Do not** touch the needle or let it touch any surfaces.
- **Do not** use the prefilled syringe if it is dropped without the needle cover in place.
- Hold the barrel of your ORENCIA prefilled syringe in one hand between the thumb and index finger (**see Figure G**).



Figure G

- **Do not** pull back on the plunger of the syringe.
- Use your other hand and gently pinch the area of skin you cleaned. Hold firmly.
- Use a quick, dart-like motion to insert the needle into the pinched skin at a 45° angle (**see Figure H**).

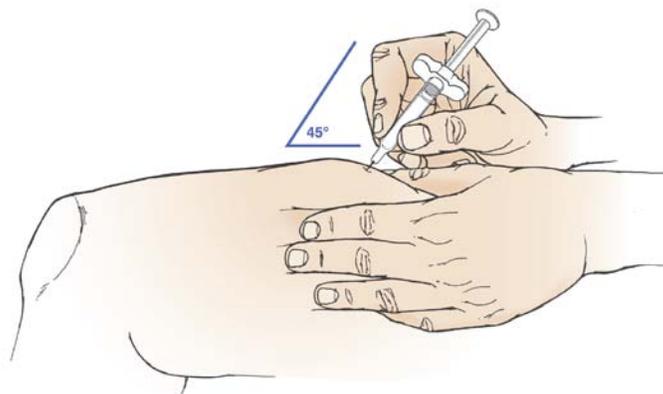


Figure H

- To inject all of the medicine, use your thumb to push down on the plunger head until the plunger head is pushed in as far as it will go (**see Figure I**).

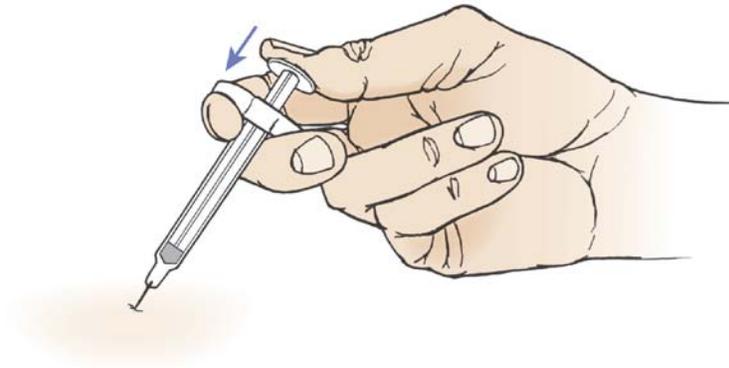


Figure I

- Remove the needle from the skin and let go of the surrounding skin.

After the Injection

- 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 a small bandage.

STEP 4: Disposal and Recordkeeping

- The ORENCIA prefilled syringe should not be reused.
- Put the used syringe into your puncture resistant container (see “**How do I throw away used syringes?**”).
- **Do not** put the needle cover back on the needle.
- **If your injection is given by another person, this person must also be careful when removing the syringe and disposing of the syringe to prevent accidental needle stick injury and passing infection.**

How do I throw away used syringes?

Check with your healthcare provider or pharmacist for instructions about the right way to throw away used syringes. There may be special local or state laws about how to throw away used syringes.

- **Do not** throw away used syringes in the household trash and do not recycle them.
- Put used and empty ORENCIA prefilled syringes in a biohazard container made specifically for disposing of used syringes (called a “sharps” container) or in a hard plastic container with a screw-on cap (such as an empty detergent bottle) or in a metal container with a plastic lid (such as a coffee can). Sharps containers can be purchased at your local pharmacy or many retail outlets.
- When the container is full, tape around the cap or lid to make sure the cap or lid does not come off.

- **Keep ORENCIA prefilled syringes and the disposal container out of the reach of children.**

Record your Injection

- Write the date, time, and specific part of your body where you injected yourself. It may also be helpful to write any questions or concerns about the injection so you can ask your healthcare provider.

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

Frequently Asked Questions

Injecting with the ORENCIA prefilled syringe

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

- When giving yourself an injection, you may feel a prick from the needle. Sometimes, the medicine can cause slight irritation near the injection site. This may happen and the 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.

Traveling with ORENCIA prefilled syringes

How should I keep my prefilled syringes cool while traveling?

- If you need to take your prefilled syringes with you, store them in a cool carrier between 36°F to 46°F (2°C to 8°C) until you are ready to use.
- **Do not** freeze ORENCIA.
- Keep ORENCIA in the original carton and protected from light. Your healthcare provider may know about special carrying cases for injectable medicines.

Can I take my prefilled syringes on an airplane?

- Generally you are allowed to carry ORENCIA prefilled syringes with you on an airplane. **Be sure to carry the prefilled syringes with you on board the plane, and do not put them in your “checked” luggage.** You should carry ORENCIA prefilled syringes 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.
- Keep ORENCIA in the original carton, with its original preprinted labels and protected from light.

What if my syringe does not stay cool for an extended period of time? Is it dangerous to use?

- Contact 1-800-ORENCIA (1-800-673-6242) for details.

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

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