

PATIENT INFORMATION
ORENCIA® (oh-REN-see-ah)
(abatacept)
injection, for intravenous or subcutaneous use

Rx ONLY

What is ORENCIA (abatacept)?

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.
- people 2 years of age and older with moderate to severe polyarticular juvenile idiopathic arthritis (pJIA). ORENCIA may be used alone or with methotrexate.
- people 2 years of age and older with active psoriatic arthritis (PsA). In adults, ORENCIA can be used alone or with other PsA treatments. In children, ORENCIA can be used alone or with methotrexate.

ORENCIA is also used for the preventative treatment of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in:

- people 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor.

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

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

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

Before you receive or use ORENCIA, tell your healthcare provider about all of your medical conditions, including 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 during treatment with 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 Patient Information leaflet for a complete list of ingredients in ORENCIA.
- have or have had inflammation of your liver due to an infection (viral hepatitis). Your healthcare provider may examine you for hepatitis before treatment with ORENCIA.
- 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. Your healthcare provider may examine you for TB or perform a skin test before treatment with ORENCIA. Symptoms of TB may include:
 - a cough that does not go away
 - fever
 - weight loss
 - night sweats
- have a history of Epstein-Barr Virus (EBV) or Cytomegalovirus (CMV) in people receiving ORENCIA for preventative treatment of aGVHD during HSCT from an unrelated donor.
- are scheduled to have surgery.
- recently received a vaccination or are scheduled for a vaccination.
- 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 healthcare provider 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 using ORENCIA subcutaneously.
- 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 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 or plan to breastfeed. It is not known if ORENCIA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you use ORENCIA.

ORENCIA® (abatacept)

- 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.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter 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 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 that may affect your immune system.

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

How will I receive or use ORENCIA?

For treatment of RA, pJIA or PsA:

- You may receive ORENCIA given by a healthcare provider through a vein in your arm (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. Intravenous administration of ORENCIA is not approved for pediatric patients with psoriatic arthritis.
- You may also receive ORENCIA as an injection under your skin (subcutaneous). For home use, ORENCIA comes in a prefilled syringe or prefilled ClickJect autoinjector. Your healthcare provider will prescribe the type that is best for you. If your healthcare provider decides that you or a caregiver can give your injections of ORENCIA prefilled syringes or ORENCIA ClickJect autoinjectors 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.

For preventative treatment of aGVHD:

- You will receive ORENCIA by a healthcare provider through a vein in your arm (intravenous infusion) over 60 minutes on the day before transplantation (Day -1). You will then receive ORENCIA on Days 5, 14, and 28 after transplantation.
- Your healthcare provider may give you antiviral medicines before, during, and after your transplantation to help prevent Epstein-Barr Virus (EBV) and Cytomegalovirus (CMV) infections.

What are the possible side effects of ORENCIA?

ORENCIA may cause serious side effects, including:

- **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 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 are treated with 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 during treatment with 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 (live vaccines). You can receive non-live vaccines, such as pneumococcal and inactivated influenza (flu) vaccines. ORENCIA may also cause some vaccinations to be less effective. Talk with your healthcare provider about your vaccination plans.

- **breathing problems in people with Chronic Obstructive Pulmonary Disease (COPD).** You 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.
- **Cytomegalovirus (CMV) and Epstein-Barr Virus (EBV) infections.** CMV and EBV infections and return of CMV and EBV (reactivation) have happened in people receiving ORENCIA for preventative treatment of aGVHD during unrelated HSCT. Your healthcare provider will monitor you for 6 months after transplantation and may treat you with medicines to help prevent CMV and EBV infection if needed.

The most common side effects of ORENCIA in people with RA include:

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

In children and adolescents, other side effects may include:

- diarrhea
- cough
- fever
- abdominal pain

The most common side effects of ORENCIA in prevention of aGVHD include:

- low red blood cell count
- high blood pressure
- CMV infection
- fever
- pneumonia
- nosebleed
- decreased CD4 lymphocytes
- increased levels of magnesium in the blood
- kidney problems

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.

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

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.

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

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

Revised: October 2023

427-US-2300213 11/23