For Adults with Active Psoriatic Arthritis (PsA)

Ask your rheumatologist if ORENCIA may help your active PsA.

What is ORENCIA?
ORENcia® (abatacept) is a prescription biologic medicine used to reduce signs and symptoms of active Psoriatic Arthritis (PsA) in adults 18 years and older. In adults, ORENCIA may be used alone or with other PsA treatments.

Ask your rheumatologist if ORENCIA may help your active PsA.

Please read the Important Facts About ORENCIA on pages 17-23.
For adults with active Psoriatic Arthritis (PsA)

Being diagnosed with active PsA can be challenging, but with appropriate treatment you may be able to find relief from your symptoms.

One of the most important things you can do is work with your rheumatologist to make sure that you are on the right treatment for you.

This guide is organized into the following sections for easy reference:

- About Psoriatic Arthritis (PsA) Pages 4-5
- How ORENCIA may help Pages 6-11
- Trial Data: Common Side Effects Pages 12-13
- How ORENCIA works Pages 14-15
- Educational Resources Page 16
- Important Facts About ORENCIA Pages 17-23

For additional information and resources, visit ORENCIA.com/psa or call us 24/7 at 1-800-ORENCIA.

WHAT IS ORENCIA?

ORENCIA® (abatacept) is a prescription biologic medicine used to reduce signs and symptoms of active Psoriatic Arthritis (PsA) in adults 18 years and older. In adults, ORENCIA may be used alone or with other PsA treatments.

ORENCIA is available in two forms:

ORENCIA intravenous (IV) infusion is given by your healthcare provider through a vein in your arm.

OR

ORENCIA subcutaneous (SC) injection is a shot that is given just under your skin. It is available as a prefilled syringe or a ClickJect™ Autoinjector.

Talk to your rheumatologist about the best way to receive ORENCIA.

Please read the Important Facts About ORENCIA on pages 17-23.
WHAT IS PsA?
PsA is a chronic inflammatory form of arthritis that can affect the skin or the joints. PsA can affect any joint in the body, including the spine. The exact cause of PsA is unknown.

SYMPTOMS
Symptoms of PsA include swelling, stiffness, and pain in and around the joints, along with changes in nails, and overall fatigue. Symptoms of PsA vary among different people. Many are common to other forms of arthritis, making the disease tricky to diagnose. You may have periods when your symptoms improve or at times become worse. Early recognition, diagnosis and treatment of PsA may help reduce signs and symptoms that occur in the disease.

A PROGRESSIVE DISEASE
PsA is an autoimmune disease, which is when the body mistakes its own tissue for a foreign invader and attacks itself. While no cure exists, managing symptoms is important.

Selected Important Facts About ORENCIA

Serious side effects
Serious side effects are those that may require medical treatment or hospitalization, cause permanent damage, or be life-threatening or sometimes even fatal. Talk to your healthcare provider about any concerns you may have.

- Infections. ORENCIA can make you more likely to get infections or make the infections that you have worse. In some cases, these infections have been fatal. Symptoms of an infection include:
  - Fever
  - Cough
  - Warm, red, or painful skin
  - Feeling very tired
  - Flu-like symptoms

Call your healthcare provider right away if you feel sick or have any of the symptoms of an infection.

For adults with active Psoriatic Arthritis (PsA)
ORENCIA — A TREATMENT OPTION FOR PsA

ORENCIA is a prescription medication for adults with active PsA. ORENCIA is a biologic disease-modifying antirheumatic drug (DMARD) that works early in the chain of events leading to inflammation in PsA.

ORENCIA OFFERS THREE ADMINISTRATION OPTIONS:

1. ORENCIA ClickJect™ Autoinjector
   - ORENCIA’s latest dosing technology: ClickJect™ Autoinjector, for once-weekly injections, an accurate and easy-to-use self-injector
   - The non-slip grip and lightweight ergonomic design of the ClickJect Autoinjector helps with handling and control
   - Large viewing window and blue indicator help confirm the full dose of ORENCIA has been injected

2. ORENCIA Prefilled Syringe
   - A self-injection (under the skin) is something you can do yourself after initial training at your doctor’s office. This once-weekly injection can also be done in the comfort of your home

3. ORENCIA Intravenous (IV) Infusion
   - An IV (through a vein) infusion of ORENCIA is given in your arm by a health care professional. This once-a-month procedure at the doctor’s office or infusion center usually takes about 30 minutes*

*Dosing at Days 1, 15, and 29 and every 4 weeks thereafter

Your doctor will discuss which option is best for you.

For adults with active Psoriatic Arthritis (PsA)

Selected Important Facts About ORENCIA

Allergic reactions. Allergic reactions can happen with ORENCIA. Symptoms of an allergic reaction may include:
   - Hives
   - Swollen face, eyelids, lips, or tongue
   - Trouble breathing

Seek urgent medical attention if you have any of the symptoms of an allergic reaction.

Please read the Important Facts About ORENCIA on pages 17-23.
CLINICAL TRIALS OVERVIEW
ORENCIA subcutaneous (SC) injection and ORENCIA intravenous (IV) infusion were both studied in adults (18 years and older) with active PsA.

ORENCIA SC was given to 424 patients with PsA and ORENCIA IV was given to 82 patients with PsA.

Patients in the clinical trials had active PsA and:
- 1 qualifying psoriatic skin lesion of at least 2 cm (about the width of a nickel)
- 3 or more tender joints
- 3 or more swollen joints

The studies included patients who were new to biologics as well as patients who have not been helped enough by biologics, such as Enbrel® (etanercept) or Humira® (adalimumab).

Selected Important Facts About ORENCIA
• If you have the hepatitis B virus, talk to your healthcare provider as hepatitis B can become an active infection while you use ORENCIA. Your rheumatologist may do blood tests before treatment with ORENCIA to check if you have hepatitis B.

UNDERSTANDING THE RESULTS
Here are two important terms to understand when reviewing clinical trial data:

Improvement in symptoms In clinical trials for PsA, “improvement in symptoms” is measured by a calculation called the ACR 20. To understand the ACR 20, let’s break it down. The ACR in ACR 20 stands for the American College of Rheumatology, which came up with the following criteria to track symptom improvement with treatment over the course of a clinical trial:
- General health information or progress (measured by both patient and physician health assessments)
- Pain scale
- Physical function (measured by Health Assessment Questionnaire Disability Index, also called HAQ-DI)
- Laboratory test results (measure the amount of inflammation in your joints)

Improvement in physical function is measured by using a patient questionnaire (HAQ-DI) for assessing common daily activities such as, dressing and grooming, arising, eating, walking, hygiene, reach, and grip.
How ORENCIA® (abatacept) may help (cont’d)

Precautions

Selected Important Facts about ORENCIA

If you are receiving or are scheduled to receive vaccinations, it is important to know that:

• You should not receive live vaccines while taking ORENCIA and for 3 months after ending treatment, as it may cause serious side effects

• ORENCIA may also cause some other vaccinations to be less effective

Talk to your rheumatologist about your vaccination plans.

Please read the Important Facts About ORENCIA on pages 17-23.

PsA Clinical Trial 1

Studied how well ORENCIA IV infusion worked in patients with active PsA who haven’t been helped enough by DMARDs

Control group
Placebo IV and +/-MTX

At 6 months, patients’ symptoms and physical function were measured.

PsA Clinical Trial 2

Studied how well ORENCIA SC worked in patients with active PsA who haven’t been helped enough by DMARDs

Control group
Placebo SC and +/-MTX

At 6 months, patients’ symptoms and physical function were measured.

Trials Data: How Might ORENCIA Work for Me?

ORENCIA has been studied in approximately 600 patients to see how well it would work in people with active PsA who have not been helped enough by the treatments they have taken, like disease-modifying antirheumatic drugs (DMARDs).

It is important to note that every patient is different. How you respond to treatment may vary from how other patients respond.

How to read these pages: With your doctor, choose the administration method — intravenous (IV) infusion or subcutaneous (SC) self-injection — that’s right for you. See below to learn about the trial results that are most relevant to you.

Selected Important Facts About ORENCIA

These are not all the possible side effects of ORENCIA. If you have any questions or want more information about side effects, ask your rheumatologist or healthcare provider.

Please read the Important Facts About ORENCIA on pages 17-23.
WHAT WERE THE COMMON SIDE EFFECTS?

The safety of ORENCIA® (abatacept) was studied in PsA trials (PsA Clinical Trial 1 and PsA Clinical Trial 2). The safety profile of ORENCIA in the PsA trials was comparable to and consistent with the safety profile seen in studies with adults living with moderate to severe Rheumatoid Arthritis.

- Headache
- High blood pressure
- Nasopharyngitis*
- Dizziness
- Heartburn
- Urinary tract infection
- Cough
- Rash
- Back pain
- Pain in extremity

* Nasopharyngitis: Inflammation of the nose and throat (characterized by sneezing, stuffy nose, cough, and sore throat).

Selected Important Facts about ORENCIA

•  If you have Chronic Obstructive Pulmonary Disorder (COPD), you may experience breathing problems more often while taking ORENCIA. Call your healthcare provider if you experience any of the following:
  •  Worsened COPD
  •  Cough
  •  Trouble breathing
THE SCIENCE BEHIND ORENCIA

T cells play a key role in your immune system, and are particularly important in the chain of events that are believed to lead to the inflammation in PsA.

In PsA, your immune system confuses some of your own cells as foreign invaders, and T cells may be mistakenly activated.

Activated T cells send signals to the other inflammatory cells of the immune system, calling them into action.

These other inflammatory cells send out signals of their own. These signals are thought to be linked to inflammation in PsA.

ORENCIA WORKS BY TARGETING A SOURCE OF PsA EARLY IN THE INFLAMMATION PROCESS

ORENCIA works by getting in the way of T cell activation, reducing the amount of signals that can be sent.

Many other DMARDs work by getting in the way of the signals that have been sent to wake up other inflammatory cells in the immune system.

Anti-inflammatory drugs decrease inflammation.

Selected Important Facts about ORENCIA

- Certain kinds of cancer (malignancies) have been reported in people using ORENCIA. It is not known if ORENCIA increases your chances of developing certain kinds of cancer.
STAY INFORMED

Understanding PsA means empowerment as a patient. Here are some resources to help you stay well-informed and may help in your treatment discussions with your health care professional.

American College of Rheumatology

Arthritis Foundation
http://www.arthritis.org/about-arthritis/types/psoriatic-arthritis/what-is-psoriatic-arthritis.php

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and NIH
https://www.niams.nih.gov/health_info/Psoriatic_Arthritis/default.asp

Bristol-Myers Squibb does not endorse these organizations. The information/links provided by Bristol-Myers Squibb are meant for informational purposes only and are not meant to replace a physician’s medical advice.

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Talk to your rheumatologist about the best way to receive ORENCIA.

(continued)

Please read the Important Facts About ORENCIA on the following pages.
What should I discuss with my rheumatologist before starting ORENCIA?

Talk to your rheumatologist about all of your medical conditions, including if:

- **You have any kind of infection**, as you may have a higher chance of getting serious side effects from an infection while taking ORENCIA. Infections include:
  - **Small infections** (such as an open cut or sore) to **whole body infections** (such as the flu).
  - **Any infection that will not go away** or a history of infections that keep coming back.
  - **Viral hepatitis**, a viral infection that affects the liver. Tell your rheumatologist if you have or have ever had viral hepatitis. Before starting ORENCIA, your rheumatologist may examine you for hepatitis.
  - **Tuberculosis (TB)**, a type of lung infection. Tell your rheumatologist if you have ever had TB or a positive skin test for TB, or have recently been in close contact with someone who has ever had TB. Before starting ORENCIA, your rheumatologist may check you for TB or do a skin test. Call your rheumatologist if you notice any symptoms of TB, including: a cough that does not go away, weight loss, fever, or night sweats.

- **You have allergies to the ingredients** of ORENCIA. For a list of ingredients, see What are the ingredients in ORENCIA? in the Patient Information section of the Full Prescribing Information.

- **You have Chronic Obstructive Pulmonary Disease (COPD)**, a type of lung disease.

- **You have diabetes**. Your healthcare provider may tell you to use a different way to monitor your blood sugar levels on the day that you receive ORENCIA IV infusion. ORENCIA IV contains maltose, which can alter the blood sugar readings with certain types of blood glucose monitors.

What should I avoid while I am on ORENCIA?

ORENCIA and other medicines may affect each other, which could cause serious side effects. **You should avoid taking ORENCIA with other biologics** that may affect your immune system. Doing so may increase your chances of getting a serious infection.

Tell your rheumatologist if you are taking other biologic medicines, such as:

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

(continued)

Please read the Important Facts About ORENCIA on the following pages.
Important Facts About ORENCIA® (abatacept) (cont’d)

What should I avoid while I am on ORENCIA?
(cont’d)

Talk to your rheumatologist and your other healthcare providers before you begin to take anything new or if you have any changes to your medications during your treatment with ORENCIA. It is a good idea to keep an up-to-date list of all of your medicines, vitamins, and herbal supplements on hand to show your doctors and pharmacists.

What are the possible side effects of ORENCIA?

This is a list of some of the possible side effects of ORENCIA for your reference.

Talk to your rheumatologist about any side effect that may be bothering you. Your rheumatologist can work with you to manage side effects throughout your treatment.

Serious side effects

Serious side effects are those that may require medical treatment or hospitalization, cause permanent damage, or be life-threatening or sometimes even fatal. Talk to your healthcare provider about any concerns you may have.

• Infections. ORENCIA can make you more likely to get infections or make the infections that you have worse. In some cases, these infections have been fatal. Symptoms of an infection include:
  • Fever
  • Cough
  • Warm, red, or painful skin

Call your healthcare provider right away if you feel sick or have any of the symptoms of an infection.

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  • Hives
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  • Trouble breathing

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• If you are receiving or are scheduled to receive vaccinations, it is important to know that:
  • You should not receive live vaccines while taking ORENCIA and for 3 months after ending treatment, as it may cause serious side effects.
  • ORENCIA may also cause some other vaccinations to be less effective.

Talk to your rheumatologist about your vaccination plans.

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  • Worsened COPD
  • Cough
  • Trouble breathing

• Certain kinds of cancer (malignancies) have been reported in people using ORENCIA. It is not known if ORENCIA increases your chances of developing certain kinds of cancer.

Please read the Important Facts About ORENCIA on the following pages.
What are the possible side effects of ORENCIA? (cont’d)

**Most common side effects**

The most common side effects of ORENCIA are:
- Headache
- Sore throat
- Upper respiratory tract infection
- Nausea

These are not all of the possible side effects of ORENCIA. If you have any questions or want more information about side effects, ask your rheumatologist or healthcare provider.

If you experience any side effects and would like to report them to the FDA, you can call 1-800-FDA-1088.

How will I receive ORENCIA? (cont’d)

ORENCIA SC injection is a shot that is given just under your skin. It is available as a prefilled syringe or ClickJect™ Autoinjector. If your rheumatologist decides that your injections can be given at home, you or your caregiver will receive training on how to prepare and inject ORENCIA. Do not try to inject ORENCIA until you have been shown the right way by your rheumatologist or healthcare provider.

You will use ORENCIA SC injection once weekly.

For more information about preparing and giving ORENCIA SC injections at home, see Instructions for Use in the Patient Information section of the Full Prescribing Information.

Please click here to read the Patient Information in the Full Prescribing Information.
Please read the Important Facts About ORENCIA on pages 17-23.