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.

Please read the Important Facts About ORENCIA on pages 17-22.
### Joints commonly affected by PsA

- Neck
- Elbows
- Shoulders
- Hands
- Wrists
- Ankle
- Hands

### About Psoriatic Arthritis (PsA)

#### Selected Important Facts About ORENCIA® (abatacept)

**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.

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*Please read the Important Facts About ORENCIA on pages 17-22.*
Early recognition, diagnosis, and treatment of PsA may help reduce signs and symptoms that occur in the disease.

Being diagnosed with active Psoriatic Arthritis (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.

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.

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

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 difficult to diagnose. You may have periods when your symptoms improve or at times become worse.
How ORENCIA® (abatacept) may help

ORENCIA is used to reduce the signs and symptoms of active PsA in adults 18 years and older.

Model, not actual patient.

Please read the Important Facts About ORENCIA on pages 17-22.
Clinical trials overview

ORENCIA® (abatacept) subcutaneous (SC) injection and ORENCIA intravenous (IV) infusion were both studied in adults (18 years and older) with active PsA.

In the ORENCIA SC trial, 213 patients were given ORENCIA SC and 211 patients were given placebo.

In the ORENCIA IV trial, 40 patients were given ORENCIA IV and 42 patients were given placebo.

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 study included patients who were new to biologics and patients who previously had an inadequate response to biologics, such as Humira® (adalimumab), Enbrel® (etanercept), and Remicade® (infliximab).

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.

For more information regarding PsA clinical trials and safety results, see pages 6-9.
Trial 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).

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.
PsA Clinical Trial 2 studied how well ORENCIA SC worked in patients with active PsA who haven’t been helped enough by DMARDs.

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

On average, the ORENCIA SC group saw:

**Greater improvement in symptoms** as measured by ACR20 at 6 months
- ORENCIA SC group: 39% improvement
- Control group: 22% improvement

**Improvement in physical function** as measured by HAQ-DI at 6 months
- ORENCIA SC group: 31% improvement
- Control group: 24% improvement

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

**Selected Important Facts About ORENCIA® (abatacept)**

- 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.
Understanding the trial information

What were the common side effects of ORENCIA® (abatacept)?
The safety profile of ORENCIA was comparable between the PsA studies and consistent with the safety profile seen in studies with adults living with moderate to severe Rheumatoid Arthritis.

What does “improvement in symptoms” mean?
In clinical trials for PsA, “improvement in symptoms” is measured by a calculation called the ACR20. To understand the ACR20, let’s break it down.
The ACR in ACR20 stands for the American College of Rheumatology, which came up with the following criteria to track symptom improvement with medication over the course of a clinical trial:

1. General health information or progress (measured by both patient and physician health assessments)
2. Pain scale
3. Physical function (measured by HAQ-DI)
4. Laboratory test results (measure the amount of inflammation in your joints)

The 20 in ACR20 refers to an improvement of at least 20% in the symptoms above — that is, 20% fewer swollen joints, 20% less pain, 20% improved lab results, etc.

Taken together, the ACR20 score describes the number of people in a trial who experienced an improvement in symptoms of at least 20%. The higher the ACR20 score, the better.

Selected Important Facts About ORENCIA

- If you have Chronic Obstructive Pulmonary Disease (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

Please read the Important Facts About ORENCIA on pages 17-22.
Imagine there were 10 participants in a clinical trial. By the end of the trial, the researchers found:

4 out of 10 people had improvements in symptoms by 20%. The remaining people had improvements in symptoms by less than 20%.

So in this example trial, the ACR20 score would be: 4 out of 10 (or 40%).

Let’s walk through an example.

What does “improvement in physical function” mean?

A patient’s assessment of their physical function is a core part of the American College of Rheumatology (ACR) criteria. The ACR criteria are a well-accepted measure of patient improvement in clinical trials.

How “improvement in physical function” is calculated

“Improvement in physical function” was calculated by comparing the patient’s Health Assessment Questionnaire Disability Index (HAQ-DI) score at the beginning of the trial to the patient’s physical function at a set time in the trial (e.g., at 6 months).

How physical function is measured

Physical function is determined by the HAQ-DI questionnaire that patients fill out. A score is calculated based on questions about the difficulty patients had in the past week with activities in eight categories, and what kind of aids they may be using for each. Scores can range from 0 to 3.

Categories

1. Dressing and grooming
2. Arising*
3. Eating
4. Walking
5. Hygiene
6. Reach
7. Grip
8. Common daily activities

Difficulty

1. Without ANY difficulty
2. With SOME difficulty
3. With MUCH difficulty
4. UNABLE to do

*Arising: standing up from a straight chair, getting in and out of bed.

Please read the Important Facts About ORENCIA on pages 17-22.
In order to understand how ORENCIA works, it’s helpful to take a closer look at some of the cells of the immune system that are particularly important to the inflammation that happens in PsA.

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.

See the science in action at ORENCIA.com/MOA
ORENCIA® (abatacept) works by targeting a source of PsA early in the inflammation process

ORENCIA is a biologic DMARD (disease-modifying antirheumatic drug) that works early in the chain of events leading to inflammation in PsA. It 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-inflammatoriees 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.
ORENCIA® (abatacept) offers 3 administration options

**ORENCIA IV infusion**
- An IV (through a vein) infusion of ORENCIA is given in your arm by a healthcare 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.

**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 procedure can also be done in the comfort of your home.

**ORENCIA ClickJect™ Autoinjector**
- ORENCIA’s newest dosing technology, the ClickJect™ Autoinjector, is an accurate and easy-to-use self-injector designed with PsA patients in mind.
- The non-slip grip and lightweight, ergonomic design of the ClickJect™ Autoinjector helps with handling and control.
- The large viewing window and blue indicator help confirm that the full dose of ORENCIA has been injected.

To learn more about ORENCIA dosing options, including Instructions for Use, visit ORENCIA.com/dosing
Knowledge is power
When you’re educated about your active PsA, you feel empowered as a patient. Staying well informed and up to date can help you get the best treatment results.

Here are some helpful resources:

Arthritis Foundation
https://www.arthritis.org

CreakyJoints, an arthritis resource community
https://www.creakyjoints.org

American College of Rheumatology (ACR)
https://www.rheumatology.org (See “Patient Information”)

This list of resources is provided as a convenience. Bristol-Myers Squibb does not endorse and is not responsible for information provided by third-party organizations.

Visit ORENCIA.com for all things ORENCIA.

Selected Important Facts About ORENCIA® (abatacept)

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.

Please read the Important Facts About ORENCIA on pages 17-22.
Comprehensive support. Human connection.
Managing your active PsA can be challenging. You may have lots of questions about the disease, ORENCIA insurance coverage, or co-pay assistance. Whether you are taking ORENCIA or another treatment, On Call™ is here to help.

ORENCIA On Call™ provides free services, including:
- 24/7 personal Care Counselors and nurse support*†
- Help understanding your ORENCIA insurance coverage
- Educational materials that may help you throughout your treatment

Financial Support
Pay as little as $5 per one-month supply
If you qualify for ORENCIA self-injection financial support:
- Your out-of-pocket drug cost may be as little as $5 per one-month supply
- For eligible commercially insured patients, the patient pays $5 out-of-pocket drug cost per one-month supply and the program covers a maximum of $15,000 in co-pays per calendar year (excluding certain dispensing costs) with monthly maximums of $4,000 for month one, $2,000 for month 2, $1,000 for months three through ten, and $500 for months eleven and twelve
- You may use the card 12 times per calendar year, up to a maximum benefit of $15,000

Eligibility requirements and Terms and Conditions apply. Please see Terms and Conditions on page 16.

Answering questions about your ORENCIA insurance coverage
Our ORENCIA Care Counselors can do an Insurance Benefits Review to look into your health insurance to understand the benefits you have for ORENCIA. Contact us to ask an ORENCIA Care Counselor for help.

*Live Chat is available 8 AM to midnight EST. ORENCIA Care Counselors are available 24/7 at 1-800-ORENCIA (1-800-673-6242). ORENCIA nurses are available for assistance Monday through Friday, 8 AM to 8 PM EST. At all other times, nurses will usually return your calls within 30 to 60 minutes. Response times may vary in Puerto Rico.
†Care Counselors and nurse support can provide general information about ORENCIA, but may not provide medical advice. Your doctor is the best source of information about your health.
Reimbursement option

If your pharmacy does not accept the ORENCIA® (abatacept) Co-pay Assistance Card, you can still receive the same benefits using the reimbursement form.

✅ Reimbursement forms can be found at ORENCIA.com or patientrebateonline.com.

✅ Enclose the original pharmacy receipt (a valid receipt should include the patient’s name, the name of the medicine purchased, the date, and the amount paid).

Be sure to circle:

- ORENCIA
- Date of purchase
- Amount paid
- Medication quantity

✅ Enclose the original receipt in the prepaid reimbursement form, seal all 3 sides, and place in mail.

Visit patientrebateonline.com for more details.
• Patients must have commercial insurance that pays for ORENCIA but does not cover the full cost; that is, you must have a co-pay obligation. Co-pay assistance is not available if your out-of-pocket expenses are $5 or less.

• Patients who have prescription insurance coverage through a state or federal healthcare program, including Medicare, Medicare Part D, Medicare Advantage, Medicaid, Tricare, Veterans Affairs (VA), or Department of Defense (DoD) programs are not eligible for this program; patients who move from commercial to federal health insurance will no longer be eligible.

• Patients who purchased their prescription drug insurance through a Health Insurance Exchange (also known as a Health Insurance Marketplace or Small Business Health Options Program (SHOP) Marketplace) are currently eligible.

• Patients or their guardian must be 18 years of age or older.

• The ORENCIA Co-pay Assistance Card must be presented at the pharmacy, along with a valid prescription for ORENCIA, at the time of purchase.

• For eligible commercially insured patients, the patient pays $5 out-of-pocket drug cost per one-month supply and the program covers a maximum of $15,000 in co-pays per calendar year (excluding certain dispensing costs) with monthly maximums of $4,000 for month one, $2,000 for month two, $1,000 for months three through ten, and $500 for months eleven and twelve.

• The Co-pay Assistance Card benefit includes 12 uses per calendar year, up to a maximum benefit of $15,000.

• The Co-pay Card must be activated before use and expires on December 31, 2019.

• Program payments are for the benefit of the patient only.

• Patients, guardians, pharmacists, and healthcare prescribers cannot seek reimbursement from health insurance or any third party for any part of the benefit received by the patient through this offer.

• Your acceptance of this offer confirms that this offer is consistent with your insurance and that you will report the value received as may be required by your insurance provider.

• Offer valid only in the United States and Puerto Rico; void where prohibited by law, taxed or restricted.

• Absent a change in Massachusetts law, effective July 1, 2019, Massachusetts residents will no longer be able to participate in this Program.

• The Co-pay Card is not transferable and is limited to 1 per patient. This offer may not be combined with any other rebate/coupon, free trial or similar offer.

• The Co-pay Card may not be sold, purchased, traded or counterfeited. Reproductions of the Co-pay Card are void.

• No membership fees.

• This offer is not conditioned on any past, present or future purchase, including refills.

• The ORENCIA Co-pay Assistance Card is not insurance.

• BMS reserves the right to modify or terminate this offer at any time without notice.
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.

- **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.

Look out for the following icons as you read:

- Talk to your rheumatologist
- Call a healthcare provider right away
- Helpful information to remember

This document is a summary of important information that you need to know in order to take ORENCIA safely. Work with your rheumatologist to make the treatment suitable and safe for you or your loved one. Keep this document in a safe place, so you can refer to it before and during your treatment.

*Please read the Important Facts About ORENCIA on pages 17-22.*
What should I discuss with my rheumatologist before starting ORENCIA?

**Tell 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.

**Tell your rheumatologist** about all of your medical treatments, including if:

- You are scheduled to have **surgery**.
- You recently received or are scheduled to receive **vaccinations**.
- You are taking:
  - Other medications for PsA.
  - Prescription medications or over-the-counter medications.
  - Vitamins or herbal supplements.

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

Let your rheumatologist know if you are a woman who is:

- Pregnant or considering pregnancy. It is not known if ORENCIA can harm an unborn baby. If ORENCIA is taken during pregnancy, talk to your healthcare provider before your baby receives any vaccines.

- Breastfeeding or planning to breastfeed. It is not known if ORENCIA passes into breast milk. Talk to your healthcare provider about the best way to feed your baby if you use ORENCIA.

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)

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.

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

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.

- **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.

- **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.

- **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.
What are the possible side effects of ORENCIA? (continued)

• If you have Chronic Obstructive Pulmonary Disease (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

• 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.

Most common side effects

The most common side effects of ORENCIA are:

• Headache
• Upper respiratory tract infection
• Sore throat
• 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?

ORENCIA is available in two forms, as intravenous (IV) infusions and as subcutaneous (SC) injections. Work with your rheumatologist to determine the right treatment plan for you.

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

- You will receive your first three infusions 2 weeks apart from each other (Weeks 0, 2, and 4). After that, you will receive an infusion every 4 weeks.
- Each infusion takes about 30 minutes, though actual time in the clinic will be longer.

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.
ORENcia® on call™ provides free services, including:

- 24/7 personal Care Counselors and nurse support*†
- Help understanding your ORENCIA insurance coverage
- Educational materials that may help you throughout your treatment

Enrolling is easy.

Call 1-800-ORENCIA
(1-800-673-6242)

Visit ORENCIA.com

*Live Chat is available 8 AM to midnight EST. ORENCIA Care Counselors are available 24/7 at 1-800-ORENCIA (1-800-673-6242). ORENCIA nurses are available for assistance Monday through Friday, 8 AM to 8 PM EST. At all other times, nurses will usually return your calls within 30 to 60 minutes. Response times may vary in Puerto Rico.

†Care Counselors and nurse support can provide general information about ORENCIA, but may not provide medical advice. Your doctor is the best source of information about your health.

Please read the Important Facts About ORENCIA on pages 17-22.