Could your child see their JIA in a different way?

A Guide to JIA, ORENCIA Treatment, and Our Patient Support Program

What is ORENCIA?
ORENCIA (abatacept) is a prescription biologic medicine used to reduce signs and symptoms of moderate to severe polyarticular Juvenile Idiopathic Arthritis (JIA) in patients 2 years of age and older. ORENCIA may be used alone or with methotrexate (MTX).

Please read the Important Facts About ORENCIA on pages 23-29.
WELCOME

As a parent, you want your child to enjoy being a kid. But if they are living with moderate to severe polyarticular JIA, even everyday activities like getting on the school bus, riding a bike, or playing with friends can be a struggle.

One of the most important things you can do is to work with your child’s rheumatologist to make sure that he or she is on the right treatment for them.

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

- About JIA Pages 4-5
- How ORENCIA® (abatacept) may help Pages 6-13
- How ORENCIA® (abatacept) works Pages 14-15
- Partnering with your doctor Pages 16-17
- The ORENCIA On Call™ patient support program Pages 18-22

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

JIA is an autoimmune disease that affects children and adolescents. Like adult Rheumatoid Arthritis (RA), JIA causes chronic pain, stiffness, and swelling of the joints. JIA is an autoimmune disease, which means it’s a disease of the immune system. The immune system works to protect the body against attacks by things like bacteria or viruses. But when it’s not working correctly — such as with JIA — the immune system can mistakenly attack your child’s body.

How JIA can impact your child

To determine how a condition such as JIA may be impacting a child’s life, rheumatologists can use a survey called the Childhood Health Assessment Questionnaire (CHAQ). The CHAQ asks questions about a child’s ability to:

- Dress themselves (put on a sweater over head) and take care of general hygiene (bathing, brushing teeth, combing hair)
- Reach for things (large game box, book)
- Grip objects (write with a pen, open a previously opened jar, turn a faucet, open a door)
- Participate in activities (ride a bike, do chores, run and play)

Treating JIA with biologic medicines

Drugs for the treatment of JIA include biologic response modifiers, more simply called biologics. Biologics for JIA are believed to interrupt the effects of substances made naturally by the immune system.

Your child’s results may vary.

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.

Please read the Important Facts About ORENCIA on pages 23-29.
How ORENCIA® (abatacept) may help

ORENCIA — A TREATMENT OPTION FOR MODERATE TO SEVERE JIA

ORENCIA is a prescription medicine for children and adolescents 2 years of age and older with moderate to severe polyarticular JIA. It may be used alone or with methotrexate (MTX).

ORENCIA can be administered in 2 different ways:

1. **ORENCIA SC (subcutaneous) injection** (for children and adolescents 2 years of age and older) is a prefilled syringe that is injected through the skin. You can administer this injection to your child right in your own home. Or, your child can self-inject, after training and if comfortable with self-injection.

2. **ORENCIA IV (intravenous) infusion** (for children and adolescents 6 years of age and older) is administered by a medical professional through a needle placed directly in the vein.

Your doctor will discuss which option is best for your child.

Learn more on pages 12 and 13.

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 23-29.

ORENCIA may help your child with everyday activities such as:

- Brushing teeth
- Combing hair
- Getting dressed
- Writing with a pen or pencil
- Riding a bicycle
- Kicking a ball

Your child’s results may vary.

Ask your doctor if ORENCIA may help your child with daily activities.
How ORENCIA® (abatacept) may help

ORENCIA IV FOR PATIENTS WITH JIA
ORENCIA for intravenous (IV) infusion was studied in 190 children and adolescents aged 6 to 17 who had moderate to severe JIA, including the following subtypes:
• Oligoarticular (involving a few joints)
• Polyarticular (involving many joints)
• Systemic with polyarticular course (with organ involvement, but not at time of study)
The study included patients who were new to biologics (70%) and patients who previously had an inadequate response to biologics, such as Enbrel® (etanercept) or Humira® (adalimumab).

The results
In this clinical trial, ORENCIA was shown to improve physical function, and to help with daily activities as measured by the CHAQ.
ORENCIA demonstrated consistent improvement in signs and symptoms across the three JIA subtypes.

Your child’s results may vary.

Side effects seen in the clinical study
• The most common infections were upper respiratory tract infection and nasopharyngitis*
• Other events that occurred in at least 5% of patients were headache, nausea, diarrhea, cough, fever, and abdominal pain
• A total of six serious adverse events (acute lymphocytic leukemia, ovarian cyst, varicella infection, disease flare [2], and joint wear) were reported during the initial 4 months of treatment with ORENCIA.

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

Moderate to Severe Juvenile Idiopathic Arthritis (JIA)

ORENCIA IV STUDY AND IMPACT ON FLARES
For 4 months, all patients were given ORENCIA IV. After that period, 122 patients who had reduced signs and symptoms were divided into 2 groups. One group continued treatment with ORENCIA, and the other group did not.

For the next 6 months, doctors assessed both groups of patients to see which had worsening signs and symptoms of JIA. In other words, they checked for flares. The risk of disease flares among patients continuing on ORENCIA was less than one-third than that of patients who had stopped treatment with ORENCIA.

Patients treated with ORENCIA IV had fewer flares compared to placebo-treated patients

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.

Please read the Important Facts About ORENCIA on pages 23-29.
How ORENCIA® (abatacept) may help

In a clinical trial, ORENCIA SC improved JIA symptoms
ORENCIA subcutaneous (SC) injection, was given to 205 patients aged 2 to 17 with moderate to severe JIA including the following sub types:

- Polyarticular (involving many joints)
- Extended Oligoarticular (involving a total of more than 4 joints after the first 6 months of disease)
- Persistent Oligoarticular (involving not more than 4 joints throughout the disease course)
- Enthesitis-Related Arthritis (swelling of the connective tissue where tendons or ligaments attach to bone)
- Systemic with polyarticular course (with organ involvement, but not at time of study)

Treatment was given once weekly for 4 months and dosing was based on body weight. Improvements in signs and symptoms were similar for ORENCIA SC and ORENCIA IV.

Side effects for ORENCIA SC in the trial were consistent with the ORENCIA IV trial. There were no reported cases of hypersensitivity reactions. Local injection-site reactions occurred at a frequency of 4.4%.

Please see pages 26-28 to learn more about possible side effects.

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 23-29.
How ORENCIA® (abatacept) may help

ORENCIA HAS 2 ADMINISTRATION OPTIONS

Here are some things to consider when discussing with your doctor which form of ORENCIA you should choose. Once you understand the options, you or your doctor can decide which delivery method is best for your child.

IV indicated for ages 6 and older

About infusions with ORENCIA IV

An ORENCIA IV infusion (into a vein) is given as a once-a-month procedure at the doctor’s office or infusion center and usually takes about 30 minutes. The infusion is given in your child’s arm. When the needle is placed, he or she may feel a pinch similar to a shot.

During the first month on ORENCIA, your child will receive a total of 3 doses. After the first dose on Day 1, the next doses will be around Days 15 and 29. Once the first 3 doses are complete, your child should receive ORENCIA every 4 weeks as directed by your child’s doctor.

ORENCIA IV has not been studied in children under the age of 6.

SC indicated for ages 2 and older

About subcutaneous injection with a prefilled syringe

ORENCIA injection is a subcutaneous injection (under the skin) with a prefilled syringe. After initial training at the doctor’s office, you or your child can do this once-weekly injection yourself in the comfort of your own home.

Do not try to inject ORENCIA until you have been shown the right way by your rheumatologist or healthcare provider.

Your doctor will determine dosing based on your child’s weight.

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 23-29.
**THE SCIENCE BEHIND ORENCIA**

To understand how ORENCIA works, it’s helpful to take a closer look at T cells, a type of white blood cell that are part of your immune system. These cells are particularly important to the inflammation that happens in JIA.

**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 JIA.

In JIA, 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 JIA.

**Disease-modifying antirheumatic drugs (DMARDs), including ORENCIA, are a group of medications that help calm the overactive immune system and inflammatory activities in the body.**

**ORENCIA works by targeting a source of JIA early in the inflammation process**

ORENCIA is a biologic DMARD that works early in the chain of events leading to inflammation in JIA. 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-inflammatories 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.
THINGS THE RHEUMATOLOGIST MAY LOOK FOR

Number of swollen joints and limited range of motion

Your doctor will look at both the number of swollen joints and the number of joints your child has trouble moving to determine how active their JIA is.

- How many swollen joints does my child have?
- How many joints have limited range of motion?
- Are there more joints affected than the last visit?
- Can my child move each affected joint more or less than the last visit?
- Is my child's JIA more active than the last visit?

CHAQ

Your rheumatologist may use the Childhood Health Assessment Questionnaire (CHAQ) to determine how JIA may be impacting your child's ability to do many daily activities.

- If my child has trouble with daily activities, what does that mean?
- How can I help them with daily activities like tying their shoes or putting on a shirt?
- Can my child run around outside with friends?

Blood work

The rheumatologist may order blood tests to check for inflammation. The erythrocyte sedimentation rate (ESR or “sed rate”) or the C-reactive protein (CRP) level may be measured. An elevated sed rate and/or CRP level indicates inflammation. The doctor may also do tests to check for positive or negative rheumatoid factor (RF), an antibody present in the blood of people with JIA.

- What is considered a normal sed rate or CRP level?
- Is my child's sed rate or CRP rate elevated or higher than it was at the last visit?
- Has my child's inflammation increased since the last visit?
- Has my child tested positive for RF?
When your child has JIA, you need all the support you can get. With the ORENCIA On Call™ support program, there’s a real person ready to help.*

When you enroll your child in the program, you’ll be assigned a Personal ORENCIA Care Counselor — someone who has experience working with parents of children who have JIA.

Look to ORENCIA On Call™ for services like:

• Assistance with financial support for eligible patients†
• Infusion and injection information, including support from a nurse‡
• 24/7 patient support,* including tips and tools for managing JIA
• An Insurance Benefits Review§ to help you understand coverage for your child

Restrictions and exclusions may apply. Bristol-Myers Squibb reserves the right to revise, revoke, or terminate these programs at any time.

*Live chat is available 9 AM to midnight ET. ORENCIA Care Counselors are available 24/7 at 1-800-ORENCIA (1-800-673-6242).
†Eligibility requirements and Terms and Conditions apply.
‡ORENCIA Care Counselors and nurses cannot provide medical advice. Your doctor is the best source of information about your health.
§Ask your doctor’s office to perform this review first. If they don’t offer this service, then contact us for help.
The ORENCIA (abatacept) on call™ Patient Support Program

Co-pay Assistance

We’re here to help you with your out-of-pocket costs* and ORENCIA® (abatacept) insurance coverage questions.

For eligible patients taking ORENCIA prefilled syringe injection, the ORENCIA Co-pay Assistance Program offers:

- $5 out-of-pocket drug cost per 1-month supply
- No monthly benefit limit
- 12 uses per calendar year, up to a maximum benefit of $15,000

Get answers about your ORENCIA insurance coverage.

Our ORENCIA Care Counselors can do an Insurance Benefits Review to look into a patient’s health insurance to understand the benefits patients have for ORENCIA. Ask your doctor’s office to perform this review first. If they don’t offer this service, then contact us to ask an ORENCIA Care Counselor for help.

*Eligibility requirements and Terms and Conditions apply.

Moderate to Severe Juvenile Idiopathic Arthritis (JIA)

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.

Complete the reimbursement form in this brochure. Additional reimbursement forms can be found at www.ORENCIA.com or www.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 the mail.

Please read the Important Facts About ORENCIA on pages 23-29.
Terms and Conditions for the ORENCIA® (abatacept) Co-pay Program for Subcutaneous Use

- 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.
- Patient pays $5 out-of-pocket drug cost per one-month supply with no monthly benefit limit.
- 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.

ORENCIA.com 1-800-ORENCIA

Important Facts About ORENCIA® (abatacept)

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. Keep this document in a safe place, so you can refer to it before and during treatment.

Look out for the following icons as you read:

Talk to your rheumatologist

Call a healthcare provider right away

Helpful information to remember

What is ORENCIA?

ORENCIA (abatacept) is a prescription biologic medicine used to reduce signs and symptoms of moderate to severe polyarticular Juvenile Idiopathic Arthritis (JIA) in patients 2 years of age and older. ORENCIA may be used alone or with methotrexate (MTX).

ORENCIA is available in two forms:

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

 ✓ ORENCIA IV is approved for children 6 years and older.

 x ORENCIA IV has not been studied in children under the age of 6.

OR

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

 ✓ ORENCIA SC prefilled syringe is available for patients 2 years and older.

 x ORENCIA ClickJect™ Autoinjector has not been studied in children under 18 years of age.

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

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 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 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.

- You are scheduled to have surgery.

- You recently received or are scheduled to receive vaccinations.

- You are taking:
  - Other medications for JIA.
  - Prescription medications or over-the-counter medications.
  - Vitamins or herbal supplements.

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 for your JIA 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 to treat JIA, such as:

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

Please read the Important Facts About ORENCIA on the following pages.
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.

• 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.

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

✓ ORENCIA IV is approved for children 6 years and older.

✗ ORENCIA IV has not been studied in children under the age of 6.

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.

✓ ORENCIA SC prefilled syringe is available for patients 2 years and older.

✗ ORENCIA ClickJect™ Autoinjector has not been studied in children under 18 years of age.

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 23-29.