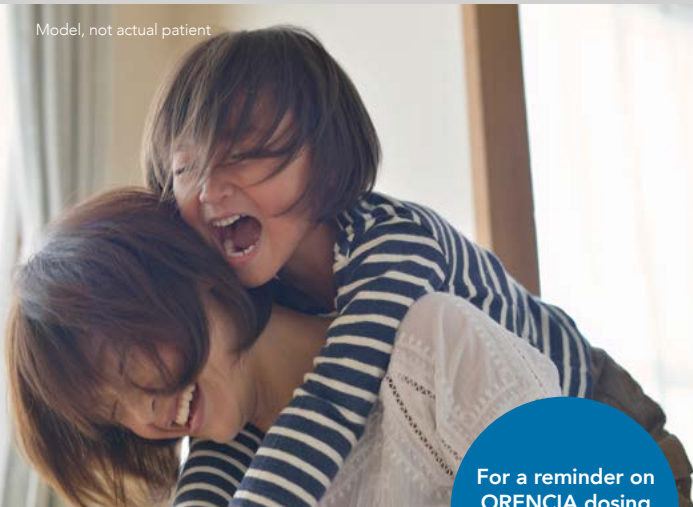


Moderate to Severe polyarticular
Juvenile Idiopathic Arthritis (pJIA)

The ORENCIA[®] (abatacept) pJIA Observational Registry

Model, not actual patient



For a reminder on
ORENCIA dosing
information, please
see page 8.

A GUIDE FOR CHILDREN, PARENTS, AND CAREGIVERS INTERESTED IN LEARNING MORE

Your child's participation in the registry can help the pJIA community better understand the long-term safety and effectiveness of ORENCIA.

Call or email to see if your child is eligible.



513-803-5349



prcsg@cchmc.org

WHAT IS ORENCIA?

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

ORENCIA should not be used with other strong medicines that affect the immune system, such as biologic disease-modifying antirheumatic drugs (bDMARDs) and Janus kinase (JAK) inhibitors.

Please [click here](#) to read the Important Facts about ORENCIA.



Model, not actual patient

What is the ORENCIA® (abatacept) pJIA Observational Registry?

This worldwide registry is designed to help the medical community understand the long-term safety and effectiveness of ORENCIA in patients with Juvenile Idiopathic Arthritis (pJIA). The registry was created at the request of the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) and is sponsored by Bristol Myers Squibb.

WHY SHOULD MY CHILD PARTICIPATE?

Participation in this registry will provide physicians, patients, regulatory authorities (FDA and EMA), and Bristol Myers Squibb with a greater understanding of pJIA and how it affects your child's daily life.

- There is no cost to participate in the registry
- Your doctor will continue to treat your child as he/she normally does
- Participation can be as long as 10 years; however, you can stop at any time

To learn how your child may be eligible to participate in this research project, contact the Pediatric Rheumatology Collaborative Study Group (PRCSG)



513-803-5349



prcsg@cchmc.org

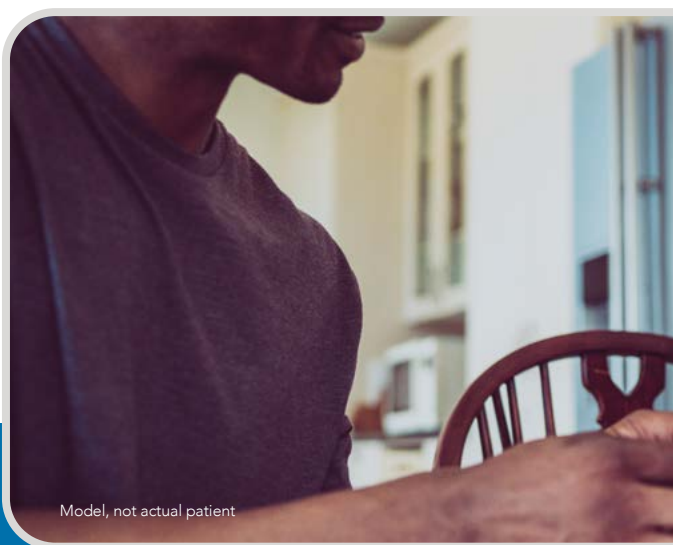
This registry is funded by Bristol Myers Squibb.

Registry participants are compensated once a year in the form of a gift card.

Is my child eligible?

The registry is currently enrolling children and adolescents who meet the following criteria:

- 1 Diagnosis of pJIA (any category)
- 2 Younger than 18 years of age at the time of enrollment
- 3 Receiving ORENCIA® (abatacept) at the time of enrollment as per the treating physician's decision
- 4 Parent or legally acceptable representative is willing to participate in the study and sign the informed consent. To learn more about informed consent, see page 6



Model, not actual patient

Your child MAY NOT be eligible if they:

- Are pregnant or nursing at the time of enrollment
- Have had a malignancy (cancer) in the past 5 years
- Have had any serious acute or chronic medical condition other than pJIA, including chronic infection, that would compromise your child's ability to participate in the study
- Have had poor compliance with clinic visits (based on physician judgment)

It is your choice to enroll your child in the ORENCIA pJIA Observational Registry. If you sign up and later decide you do not want to continue, you may stop. Simply tell your child's doctor. Being in the registry does not affect your child's medical treatment.

For more information about eligibility for the ORENCIA pJIA Observational Registry, please contact the Pediatric Rheumatology Collaborative Study Group (PRCSG)



513-803-5349



prcsg@cchmc.org



What is informed consent?

Before your child can participate in the ORENCIA® (abatacept) pJIA Observational Registry, you must first give informed consent. By giving your consent, you confirm that you understand the purpose of the registry, you volunteer to participate, and you agree to have information about your child collected. This step is a very important part of the enrollment process.

HOW DO I GIVE INFORMED CONSENT?

- Should you decide to inquire about participation in this research project, a member of the study team will discuss the registry and its benefits and risks with you and your child in language you can both understand
- You will be able to ask questions and discuss any concerns you may have about participation
- If you decide participation is right for you and your child, you will sign consent documents
- Emancipated minors (for example, some adolescents who are 16 years of age or older) will sign their own consent documents

To learn how your child may be eligible to participate in this research project, contact the Pediatric Rheumatology Collaborative Study Group (PRCSG)



513-803-5349



prcsg@cchmc.org



Model, not actual patient

Giving your child ORENCIA® (abatacept) IV or SC

YOU AND YOUR CHILD HAVE A CHOICE

ORENCIA for pJIA can be given in 2 different ways: intravenous (IV) infusion or subcutaneous (SC) injection.

IV administration is indicated for patients 6 years of age and older



ABOUT INFUSIONS WITH ORENCIA IV

An ORENCIA IV infusion (into a vein) is given once a month at the doctor's office or infusion center. The infusion usually takes about 30 minutes and 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 given 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 6 years of age.

Learn more about ORENCIA SC at
[ORENCIA.com/what-is-polyarticular-juvenile-idiopathic-arthritis](https://www.orencia.com/what-is-polyarticular-juvenile-idiopathic-arthritis)

SC administration is indicated for patients 2 years of age and older



ABOUT SC INJECTION WITH A PREFILLED SYRINGE

ORENCIA injection is an SC 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. PJA patients may self-inject with ORENCIA or the patient's caregiver may administer ORENCIA if both the healthcare practitioner and the parent/legal guardian determine it is appropriate. The ability of pediatric patients to self-inject with the autoinjector has not been tested.

Learn more about ORENCIA SC at [ORENCIA.com/what-is-polyarticular-juvenile-idiopathic-arthritis](https://www.orencia.com/what-is-polyarticular-juvenile-idiopathic-arthritis)

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.

Important Facts About ORENCIA® (abatacept)

This is a summary of important information that you need to know in order to take ORENCIA safely. Work with the rheumatologist to make the treatment suitable and safe for you or your loved one. Keep this information, so you can refer to it before and during your 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 (pJIA) in patients 2 years of age and older. ORENCIA may be used alone or with methotrexate (MTX).

ORENCIA should not be used with other strong medicines that affect the immune system, such as biologic disease-modifying antirheumatic drugs (bDMARDs) and Janus kinase (JAK) inhibitors.

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 patients 6 years and older.



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

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.



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



PJIA patients may self-inject with ORENCIA or the patient's caregiver may administer ORENCIA if both the healthcare practitioner and the parent/legal guardian determines it is appropriate.



The ability of pediatric patients to self-inject with the autoinjector has not been tested.



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

(continued)

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

Important Facts About ORENCIA® (abatacept) (cont'd)

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.
- You have a family or personal history of **skin cancer**, or see any growths or changes in the appearance of your skin during or after treatment with ORENCIA. Some people treated with ORENCIA have developed skin cancer.

(continued)

Important Facts About ORENCIA® (abatacept) (cont'd)

What should I discuss with my rheumatologist before starting ORENCIA? (cont'd)



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**. If you are receiving ORENCIA, and for 3 months after you stop receiving ORENCIA, you should not take live vaccines.
- You are taking:
 - **Other medications for pJIA.**
 - **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.
 - 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 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 pJIA** 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 pJIA**, 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
- 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.

(continued)

Important Facts About ORENCIA® (abatacept) (cont'd)

What are the possible side effects of ORENCIA? (cont'd)

- **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.
 - You can receive non-live vaccines, such as pneumococcal and inactivated influenza (flu) vaccines
 - 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 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
- **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.

(continued)

Important Facts About ORENCIA® (abatacept) (cont'd)

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**

In **children and adolescents**, other side effects may include:

- **Diarrhea**
- **Fever**
- **Cough**
- **Abdominal pain**

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 or your child.



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.

(continued)

Important Facts About ORENCIA® (abatacept) (cont'd)

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.

- ✓ ORENCIA SC prefilled syringe is available for patients 2 years and older.
- ✓ PJIA patients may self-inject with ORENCIA or the patient's caregiver may administer ORENCIA if both the healthcare practitioner and the parent/legal guardian determine it is appropriate.
- ✗ The ability of pediatric patients to self-inject with the autoinjector has not been tested.

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 Full Prescribing Information

To learn how your child may be eligible to participate in this research project, contact the Pediatric Rheumatology Collaborative Study Group (PRCSG)



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This registry is funded by Bristol Myers Squibb.

