Moderate to Severe Juvenile Idiopathic Arthritis (JIA)

The ORENCIA® (abatacept) JIA Observational Registry

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

Your child's participation in the registry can help the JIA 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 (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 10-16.
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 (JIA). 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 JIA 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

**What is the ORENCIA® (abatacept) JIA Observational Registry?**

This registry is funded by Bristol-Myers Squibb.

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 JIA (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

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 JIA, 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 JIA 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 JIA 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) JIA 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)

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Model, not actual patient
Giving your child
ORENCIA® (abatacept) IV or SC

YOU AND YOUR CHILD HAVE A CHOICE
ORENCIA for JIA can be given in 2 different ways: intravenous (IV) infusion or subcutaneous (SC) injection.

**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.

**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. The safety and efficacy of ORENCIA ClickJect™ Autoinjector for subcutaneous injection has not been studied in patients under 18 years of age.

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

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

OR

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 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.
- 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? (cont’d)

Tell 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? (cont’d)

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
  - Feeling very tired
  - Cough
  - Flu-like symptoms
  - Warm, red, or painful skin

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

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

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

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

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

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.

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

✗ 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 read the Patient Information in the Full Prescribing Information, at ORENCIA.com.

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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