

# ORENCIA®

## (abatacept)

### Patient Information

Rx only

This leaflet tells you about ORENCIA (pronounced oh-REN-see-ah). Please read this information before you start using ORENCIA and each time before you are scheduled to receive ORENCIA, in case something has changed. The information in this leaflet does not take the place of talking with your doctor before you start receiving this medicine and at check ups. Talk to your doctor if you have any questions about your treatment with ORENCIA.

#### What is ORENCIA (abatacept)?

ORENCIA is a medicine that is used to treat adults with moderate to severe rheumatoid arthritis (RA) who have not been helped by other medicines for RA. RA is a disease that causes pain and joint inflammation (tenderness and swelling). RA can also cause joint damage. Your doctor has decided to treat you with ORENCIA because your disease is still active even though you may have tried other treatments.

#### How does ORENCIA work?

ORENCIA is a medicine that keeps the immune system from attacking healthy tissues in the body. The immune system defends the body against infections caused by bacteria and viruses. A normal immune system leaves healthy body tissues alone. In people with RA, the immune system attacks normal body tissues causing damage and inflammation especially in the tissues of your joints. ORENCIA interferes with an important step in this attack. By decreasing the immune system's attack on normal tissues, ORENCIA can reduce pain and joint inflammation, and slow the damage to your bones and cartilage. However, ORENCIA can also lower your body's ability to fight infection. ORENCIA treatment can make you more prone to getting infections or make any infection you have worse. It is important to tell your doctor if you think you have any infections.

#### Who should not receive ORENCIA?

Talk to your doctor if you have ever had an allergic reaction to ORENCIA to determine if you should receive ORENCIA again.

#### What should I tell my doctor before treatment with ORENCIA?

Before you receive treatment with ORENCIA you should tell your doctor if you:

- are taking a TNF blocker such as Enbrel®, Humira®, or Remicade® to treat RA. You may have a higher chance of getting a serious infection if you take ORENCIA with other biologic medications for RA.
- are taking Kineret®.
- have any kind of infection including an infection that is in only one place in your body (such as an open cut or sore), or an infection that is in your whole body (such as the flu). Having an infection could put you at risk for serious side effects from ORENCIA. If you are unsure, please ask your doctor.
- have an infection that won't go away or a history of infections that keep coming back.
- have had tuberculosis (TB), a positive skin test for TB, or if you recently have been in close contact with someone who has had TB. If you develop any of the symptoms of TB (a dry cough that doesn't go away, weight loss, fever, night sweats) call your doctor right away. Before you start ORENCIA, your doctor may examine you for TB or perform a skin test.
- have a history of chronic obstructive pulmonary (lung) disease (COPD).
- are scheduled to have surgery.
- recently received a vaccination or are scheduled for any vaccination.
- are pregnant or planning to become pregnant. It is not known if ORENCIA can harm your unborn baby.
- are breast-feeding. ORENCIA can pass into breast milk. You will need to decide to either breast-feed or receive treatment with ORENCIA, but not both.
- have diabetes and are using a blood glucose monitor to check your blood glucose levels. ORENCIA contains maltose, which is a type of sugar that can give falsely high blood glucose readings with certain types of blood glucose monitors. Your doctor may recommend a different method for monitoring your blood glucose levels.

If you are not sure or have any questions about any of this information, ask your doctor.

#### What important information do I need to know about side effects with ORENCIA (abatacept)?

Like all medicines that affect your immune system, ORENCIA can cause serious side effects. The possible serious side effects include:

- **Serious infections.** Patients taking ORENCIA are at increased risk for developing infections including pneumonia, and other infections caused by viruses, bacteria, or fungi. Call your doctor immediately if you feel sick or get any infection during treatment with ORENCIA.
- **Allergic reactions. These reactions are usually mild or moderate** and include hives, swollen face, eyelids, lips, tongue, throat, or trouble breathing.
- **Malignancies. There have been rare cases of certain kinds of cancer in patients receiving ORENCIA. The role of ORENCIA in the development of cancer is not known.**

#### What are the more common side effects with ORENCIA?

- The more common side effects with ORENCIA are headache, upper respiratory tract infection, sore throat, and nausea.

#### Can I receive ORENCIA if I am pregnant or breast-feeding?

ORENCIA has not been studied in pregnant women or nursing mothers, so we don't know what the effects are on pregnant women or nursing babies. You should tell your doctor if you are pregnant, become pregnant, or are thinking about becoming pregnant.

#### Can I receive ORENCIA if I am taking other medicines for my RA or other conditions?

Yes, you can take other medicines if your doctor has prescribed them or has told you it is okay to take them while you are receiving ORENCIA. It is important to tell your doctor if you are taking any other medicines including hormones, over-the-counter medicines, vitamins, supplements, or herbal products before you are treated with ORENCIA. If you start taking or plan to start taking any new medicine while you are receiving ORENCIA, tell your doctor. ORENCIA should not be taken with biologic medications for RA such as Enbrel®, Humira®, Remicade®, or Kineret®.

#### How will ORENCIA be given to me?

ORENCIA will be given to you by a healthcare professional using an IV. This means the medicine will be given to you through a needle placed in a vein in your arm. It will take about 30 minutes to give you the full dose of medicine.

#### How often will I receive ORENCIA?

You will receive your first dose of ORENCIA followed by additional doses at 2 and 4 weeks after the first dose. You will then receive a dose every 4 weeks.

#### What should I do if I miss a dose of ORENCIA?

If you miss receiving ORENCIA when you are supposed to, ask your doctor when to schedule your next dose.

#### What if I still have questions?

If you have any questions or problems, always talk with your doctor. You can also call 1-800-ORENCIA™ toll-free or visit the ORENCIA internet site at [www.ORENCIA.com](http://www.ORENCIA.com) or the company internet site at [www.BMS.com](http://www.BMS.com).

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