

17.7 FDA-Approved Patient Labeling

PATIENT INFORMATION

ORENCIA[®] (oh-REN-see-ah) (abatacept)

Read this Patient Information before you start receiving ORENCIA and each time before you are scheduled to receive ORENCIA. The information may have changed. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

What is ORENCIA?

ORENCIA is a prescription medicine that reduces signs and symptoms in:

- adults with moderate to severe rheumatoid arthritis (RA), including those who have not been helped enough by other medicines for RA. ORENCIA may prevent further damage to your bones and joints and may help your ability to perform daily activities.
- children and adolescents 6 years of age and older with moderate to severe polyarticular juvenile idiopathic arthritis (JIA).

In RA and JIA, ORENCIA can reduce pain and joint inflammation, but it can also make your immune system less able to fight infection. ORENCIA can make you more likely to get infections or make any infection you have worse. It is important to tell your doctor if you think you have any infections.

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

What should I tell my doctor before treatment with ORENCIA?

Before you receive ORENCIA you should tell your doctor about all your medical conditions, including if you:

- have any kind of infection even if it is small (such as an open cut or sore), or an infection that is in your whole body (such as the flu). If you have an infection when taking ORENCIA, you may have a higher chance for getting serious side effects.
- have an infection that will not go away or a history of infections that keep coming back.
- have had tuberculosis (TB), a positive skin test for TB, or you recently have been in close contact with someone who has had TB. If you get 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 or have had viral hepatitis. Before you use ORENCIA, your doctor may examine you for hepatitis.
- have a history of chronic obstructive pulmonary (lung) disease (COPD).
- are scheduled to have surgery.
- are allergic to any of the ingredients in ORENCIA. See the end of this leaflet for a list of the ingredients in ORENCIA.
- recently received a vaccination or are scheduled for any vaccination. If you are receiving ORENCIA, you should not take live vaccines.
- have diabetes and use a blood glucose monitor to check your blood sugar (blood glucose) levels. ORENCIA contains maltose, a type of sugar that can give false high blood sugar readings with certain types of blood glucose monitors, on the day of ORENCIA infusion. Your doctor may tell you to use a different way to monitor your blood sugar levels.
- are pregnant or planning to become pregnant. It is not known if ORENCIA can harm your unborn baby.

Bristol-Myers Squibb Company has 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. Patients are encouraged to call the registry themselves or ask their doctors to contact the registry for them by calling 1-877-311-8972.

- are breast-feeding. ORENCIA can pass into breast milk. Women who are breast-feeding should talk to their doctor about whether or not to use ORENCIA.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Do not start taking any new medicine without talking with your doctor.

Especially tell your doctor if you take other biologic medicines to treat RA or JIA that may affect your immune system, such as:

- Enbrel[®] (etanercept)
- Humira[®] (adalimumab)
- Remicade[®] (infliximab)
- Kineret[®] (anakinra)
- **Rituxan[®] (rituximab)**

You may have a higher chance of getting a serious infection if you take ORENCIA with other biologic medicines for your RA or JIA.

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new prescription.

How will I receive ORENCIA?

- You will be given ORENCIA by a healthcare provider through a needle placed in a vein (IV or intravenous infusion) in your arm. It takes about 30 minutes to give you the full dose of medicine.
- You will receive ORENCIA 2 weeks and 4 weeks after the first dose. You will then receive ORENCIA every 4 weeks.
- If you miss your appointment to receive ORENCIA, ask your doctor when to schedule your next dose.

What are the possible side effects of ORENCIA?

ORENCIA can cause serious side effects including:

- **Serious infections.** Patients receiving ORENCIA have a higher chance of getting infections including pneumonia, and other infections caused by viruses, bacteria, or fungi. Call your doctor right away if you feel sick or get any of the following symptoms of infection, which may be early signs of a serious infection:
 - a fever
 - feel very tired
 - have a cough
 - have flu-like symptoms
 - warm, red, or painful skin
- **Allergic reactions.** Allergic reactions can happen on the day of treatment or the day after receiving ORENCIA. Tell your doctor or get emergency medical help right away if you have hives, swollen face, eyelids, lips, tongue, throat, or trouble breathing.
- **Cancer (malignancies).** Certain kinds of cancer have been reported in patients receiving ORENCIA. It is not known if ORENCIA increases your chance of getting certain kinds of cancer.
- **Vaccinations.** You should not receive ORENCIA with certain types of vaccines (live vaccines). ORENCIA may also cause some vaccinations to be less effective. Talk with your doctor about your vaccination plans.
- **Respiratory problems in patients with Chronic Obstructive Pulmonary Disease (COPD).** You may get certain respiratory problems more often if you receive ORENCIA and have COPD, including:
 - worsened COPD
 - pneumonia

- cough
- trouble breathing

Common side effects of ORENCIA in both adults and children include:

- headache
- upper respiratory tract infection
- sore throat
- nausea

In children, other side effects may include:

- diarrhea
- cough
- fever
- abdominal pain

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of ORENCIA. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about ORENCIA

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use ORENCIA for a condition for which it was not prescribed.

This patient information leaflet summarizes the most important information that you need to know about ORENCIA. If you would like more information, talk to your doctor.

You can ask your pharmacist or doctor for information about ORENCIA that is written for health professionals. For more information, go to www.ORENCIA.com or the company internet site at www.BMS.com or call 1-800-ORENCIA™ toll-free.

What are the ingredients in ORENCIA?

Active ingredient: abatacept

Inactive ingredients: maltose, monobasic sodium phosphate, sodium chloride for administration

Enbrel[®], Humira[®], Remicade[®], Kineret[®], and Rituxan[®] are trademarks of their respective companies.

Bristol-Myers Squibb Company
Princeton, New Jersey 08543 USA

Rev April 2008