

ORENCIA® (abatacept) Important Safety Information

Indication and Usage

ORENCIA® (abatacept) 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.

ORENCIA can also make your immune system less able to fight infections, so you may be more likely to get infections or any infection you have may get worse. It is important to tell your doctor if you think you have any infections.

Important Safety Information About ORENCIA® (abatacept)

Before you receive treatment with ORENCIA, a lyophilized powder for intravenous infusion, 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).
- 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 if 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 following ingredients in ORENCIA: abatacept, maltose, monobasic sodium phosphate, or sodium chloride for administration.
- recently received a vaccination or are scheduled for any vaccination. You should not take live vaccines if you are receiving ORENCIA.
- have diabetes and use a blood glucose monitor to check your sugar levels. The infusion of ORENCIA contains maltose, a sugar that can give falsely high blood glucose readings with some monitors on the day you receive your infusion. Your doctor may tell you to use a different way to monitor your blood sugar levels.
- are pregnant, planning to become pregnant, or are thinking about becoming pregnant. It is not known if ORENCIA can harm your unborn baby.
- are breast-feeding. You will need to decide to either breast-feed or receive treatment with ORENCIA, but not both.
- **take any other kinds of medicine**, including prescription and nonprescription medicines, vitamins, and herbal supplements.
- are taking other biologic medicines to treat RA such as: Enbrel® (etanercept), Humira® (adalimumab), Remicade® (infliximab), Kineret® (anakinra) or Rituxan® (rituximab). You may have a higher chance of getting a serious infection if you take ORENCIA with other biologic medicines.

Possible Side Effects of ORENCIA®(abatacept)

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 immediately if you feel sick or get any of the following signs of infection: fever, feel very tired, cough, feel flu-like, or 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. ORENCIA may cause some vaccinations to be less effective.
- **Respiratory problems in patients with COPD.** You may get certain respiratory problems more often if you receive ORENCIA and have COPD, including: worsened COPD, pneumonia, cough, or trouble breathing.

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

[Please read the Patient Information in the Full Prescribing Information.](#)

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