

## Indication and Important Safety Information for ORENCIA® (abatacept)

### Indication

ORENCIA is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more disease-modifying, anti-rheumatic drugs (DMARDs), such as methotrexate (MTX) or tumor necrosis factor (TNF) antagonists. ORENCIA may be used as monotherapy or concomitantly with DMARDs other than TNF antagonists.

ORENCIA should not be administered concomitantly with TNF antagonists. ORENCIA is not recommended for use concomitantly with other biologic RA therapy, such as anakinra.

### Important Safety Information

- **Concomitant use with TNF antagonists:** Concurrent therapy with ORENCIA and a biologic DMARD is not recommended. In controlled clinical trials, patients receiving concomitant ORENCIA and TNF antagonist therapy experienced more infections (63%) and serious infections (4.4%) compared to patients treated with only TNF antagonists (43% and 0.8%, respectively), without an important enhancement of efficacy
- **Hypersensitivity:** Less than 1% of patients treated with ORENCIA experienced hypersensitivity reactions, including some cases of anaphylaxis or anaphylactoid reactions. Other events potentially associated with drug hypersensitivity, such as hypotension, urticaria, and dyspnea, each occurred in less than 0.9% of patients treated with ORENCIA and generally occurred within 24 hours of infusion. Appropriate medical support measures for treating hypersensitivity reactions should be available for immediate use in the event of a reaction
- **Infections:** Caution should be exercised in patients with a history of infection or underlying conditions which predispose them to infections. Treatment with ORENCIA should be discontinued if a patient develops a serious infection. Patients should be screened for tuberculosis, and viral hepatitis in accordance with published guidelines, and if positive treated according to standard medical practice prior to therapy with ORENCIA
- **Immunizations:** Live vaccines should not be given concurrently with ORENCIA or within three months of its discontinuation as it may blunt the effectiveness of some immunizations
- **Use in Patients with Chronic Obstructive Pulmonary Disease (COPD):** COPD patients treated with ORENCIA developed adverse events more frequently than those treated with placebo (97% vs 88%, respectively). Respiratory disorders occurred more frequently in patients treated with ORENCIA compared to those on placebo (43% vs 24%, respectively), including COPD exacerbations, cough, rhonchi, and dyspnea. A greater percentage of patients treated with ORENCIA developed a serious adverse event compared to those on placebo (27% vs 6%), including COPD exacerbation (3 of 37 patients [8%]) and pneumonia (1 of 37 patients [3%]). Use of ORENCIA in patients with RA and COPD should be undertaken with caution, and such patients monitored for worsening of their respiratory status

- **Blood Glucose Testing:** ORENCIA contains maltose, which may result in falsely elevated blood glucose readings on the day of infusion when using blood glucose monitors with test strips utilizing glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ). Consider using monitors and advising patients to use monitors that do not react with maltose
- **Pregnant and Nursing Mothers:** ORENCIA should be used during pregnancy only if clearly needed. The risk for development of autoimmune diseases in humans exposed *in utero* to abatacept has not been determined. Nursing mothers should be informed of the risk/benefit of continued breast-feeding or discontinuation of the drug
- **Most serious adverse reactions:** serious infections (3% ORENCIA vs 1.9% placebo) and malignancies (1.3% ORENCIA vs 1.1% placebo)
- **Malignancies:** The overall frequency of malignancies was similar between patients treated with ORENCIA or placebo. However, more cases of lung cancer were observed in patients treated with ORENCIA (0.2%) than those on placebo (0%). A higher rate of lymphoma was seen compared to the general population; however, patients with RA, particularly those with highly active disease, are at a higher risk for the development of lymphoma. The potential role of ORENCIA in the development of malignancies in humans is unknown
- **Most frequent adverse events ( $\geq 10\%$ ):** headache, upper respiratory tract infection, nasopharyngitis, and nausea

**Please see Full Prescribing Information**