



October 16, 2013

Updated Product Information

Bristol-Myers Squibb (BMS) is announcing an update for ORENCIA® (abatacept) Subcutaneous (SC) Injection. The current ORENCIA Prefilled Syringe will be replaced by the ORENCIA Prefilled Syringe with UltraSafe Passive® Needle Guard (Safety Syringe Device) in November. The current ORENCIA Prefilled Syringe will no longer be available once supplies are depleted –only the ORENCIA Prefilled Syringe with UltraSafe Passive® Needle Guard will be available.

The updated syringe is the only change to the product at this time. There are no changes to the formulation of ORENCIA, quantity, dosing, storage and handling, needle size, injection preparation, disposal process, or price.

The transition to the new NDC is expected to occur the week of November 18, 2013. As we get closer to the transition, we will provide greater clarity on a specific introduction date.

Product information for the **CURRENT ORENCIA SC Prefilled Syringe:**

10-digit NDC	11-digit NDC	Product Name	Generic Name	Description
0003-2188-31	00003-2188-31	ORENCIA	Abatacept	125 mg in 1 mL prefilled syringe, pack of 4 syringes

Product information for the **NEW ORENCIA SC in a Prefilled Syringe with UltraSafe Passive® Needle Guard:**

10-digit NDC	11-digit NDC	Product Name	Generic Name	Description
0003-2188-11	00003-2188-11	ORENCIA	Abatacept	125 mg in 1 mL prefilled syringe with UltraSafe Passive Needle Guard, pack of 4 syringes

As inventories of the original prefilled syringe are depleted, shipments of the Safety Syringe Device to wholesalers will begin. Unexpired units of the current prefilled syringes should be dispensed and used until supply is exhausted, as BMS will not be accepting returns on previously purchased product.

The current listed WAC of \$2363.85 for the 4 count commercial package of 125 mg in 1 mL prefilled syringes will not change with the transition to the Safety Syringe Device.

Please see Important Safety Information on following pages.



Indication/Usage and Important Safety Information for ORENCIA® (abatacept)

Indication and Usage

Adult Rheumatoid Arthritis (RA): ORENCIA® (abatacept) 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 RA. ORENCIA may be used as monotherapy or concomitantly with disease-modifying, anti-rheumatic drugs (DMARDs) other than tumor necrosis factor (TNF) antagonists.

Important Limitations of Use: ORENCIA should not be administered concomitantly with TNF antagonists, and 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, adult patients receiving concomitant intravenous 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: Anaphylaxis or anaphylactoid reactions can occur during or after an infusion and can be life-threatening. In controlled, double-blind and open-label clinical trials, anaphylaxis and anaphylactoid reactions were reported in <0.1% of adult patients dosed with intravenous ORENCIA. Other reactions potentially associated with drug hypersensitivity, such as hypotension, urticaria, and dyspnea, that occurred within 24 hours of ORENCIA infusion, were uncommon (<1% each). In postmarketing experience, a case of fatal anaphylaxis following the first infusion of ORENCIA was reported. Appropriate medical support measures for treating hypersensitivity reactions should be available for immediate use. If an anaphylactic or other serious allergic reaction occurs, administration of ORENCIA should be stopped immediately and permanently discontinued, with appropriate therapy instituted.

Infections: Serious infections, including sepsis and pneumonia, have been reported in patients receiving ORENCIA. Some of these infections have been fatal. Many of the serious infections have occurred in patients on concomitant immunosuppressive therapy which in addition to their underlying disease, could further predispose them to infection. Caution should be exercised in patients with a history of infection or underlying conditions which may 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 3 months of its discontinuation as it may blunt the effectiveness of some immunizations.

Please see Important Safety Information continued on next page.

Important Safety Information for ORENCIA[®] (abatacept) continued.

Use in Patients with Chronic Obstructive Pulmonary Disease (COPD): Adult COPD patients treated with ORENCIA[®] (abatacept) 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 for intravenous administration 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, such as those based on glucose dehydrogenase nicotinic adenine dinucleotide (GDH-NAD), glucose oxidase or glucose hexokinase test methods. ORENCIA for subcutaneous (SC) administration does not contain maltose; therefore, patients do not need to alter their glucose monitoring.

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. A pregnancy registry has been established to monitor fetal outcomes. Healthcare professionals are encouraged to register pregnant patients exposed to ORENCIA by calling 1-877-311-8972.

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 adult 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 (≥10%): Headache, upper respiratory tract infection, nasopharyngitis, and nausea were the most commonly reported adverse events in the adult RA clinical studies.

Note concerning SC ORENCIA: The safety and efficacy of SC ORENCIA has not been studied in patients under 18 years of age.

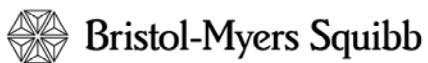
Please see accompanying Full Prescribing Information.



The ORENCIA® (abatacept) US Full Prescribing Information is enclosed for your review.

If you have any questions about ORENCIA or the new Safety Syringe Device, please contact your BMS Specialty Account Executive (SAE) or call 1-800-ORENCIA (1-800-673-6242).

Please see accompanying Full Prescribing Information.



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