INFUSING
ORENCIA® (abatacept) IV

Your go-to guide for preparing and administering an ORENCIA intravenous (IV) infusion

INDICATION AND USAGE

Adult Rheumatoid Arthritis: ORENCIA® (abatacept) is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA).

Limitations of Use: The concomitant use of ORENCIA with other potent immunosuppressants [e.g., biologic disease-modifying antirheumatic drugs (bDMARDS), Janus kinase (JAK) inhibitors] is not recommended.

Please see Important Safety Information on page 11.

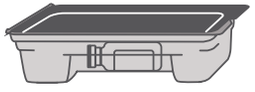
ORENCIA®
(abatacept)
Injection for Intravenous Use
Injection for Subcutaneous Use

GENERAL ADMINISTRATION

Calculate the ORENCIA dose, the total volume of reconstituted solution required, and the number of ORENCIA vials needed. For a full dose, less than the full contents of one vial or more than one vial may be needed.

A few important considerations when preparing and administering ORENCIA® (abatacept) IV

WHEN MIXING AN ORENCIA INFUSION, USE ONLY THE SILICONE-FREE DISPOSABLE SYRINGE PROVIDED WITH EACH VIAL.



ORENCIA packaging should be protected from light.

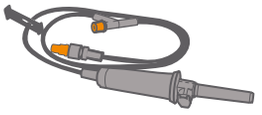
Refrigerate ORENCIA powder at 36°F–46°F, and store in the original packaging until use.

Note: After dilution, ORENCIA IV can be used immediately, refrigerated at 36°F–46°F, or stored at room temperature. ORENCIA must be administered within 24 hours of reconstitution.

Be sure to closely inspect the packaging and vials before use. Do not use the vial beyond the expiration date. If there are any product defects, call 1-800-ORENCIA to receive a new vial.

Administer ORENCIA IV within **24 hours** of reconstitution. Discard if not administered within 24 hours.

ORENCIA IV should be administered as a 30-minute infusion.



When administering ORENCIA, use an infusion set and a sterile, nonpyrogenic, low-protein–binding filter (pore size of 0.2 to 1.2 µm).

Note: Do not infuse ORENCIA IV in the same IV line with other agents.

SELECTED IMPORTANT SAFETY INFORMATION

Increased Risk of Infection with Concomitant Use with TNF Antagonists, Other Biologic RA/PsA Therapy, or JAK Inhibitors: Concurrent therapy with ORENCIA and a TNF antagonist is not recommended. In controlled clinical trials, adult RA patients receiving concomitant intravenous ORENCIA and TNF antagonist therapy experienced more infections (63% vs 43%) and serious infections (4.4% vs 0.8%) compared to patients treated with only TNF antagonists, without an important enhancement of efficacy. Additionally, concomitant use of ORENCIA with other biologic RA/PsA therapy or JAK inhibitors is not recommended.

ORENCIA® (abatacept)
Injection for Intravenous Use
Injection for Subcutaneous Use

Please see Important Safety Information on page 11.

WEIGHT-BASED DOSING

Each vial contains 250 mg of ORENCIA® (abatacept) lyophilized powder.
Based on your patient's weight, the appropriate dose may require 2, 3, or 4 vials.

Use this table to determine the correct dose for each patient based on their weight

WEIGHT:	NUMBER OF ORENCIA VIALS USED:
<132 lb	2 VIALS (500 mg)
132–220 lb	3 VIALS (750 mg)
>220 lb	4 VIALS (1000 mg)

SELECTED IMPORTANT SAFETY INFORMATION

Hypersensitivity Reactions: There were 2 cases (<0.1%; n=2688) of anaphylaxis reactions in clinical trials with adult RA patients treated with intravenous ORENCIA. Other reactions potentially associated with drug hypersensitivity, such as hypotension, urticaria, and dyspnea, each occurred in <0.9% of patients. In postmarketing experience, fatal anaphylaxis following the first infusion of ORENCIA and life-threatening cases of angioedema have been reported. Angioedema has occurred as early as after the first dose of ORENCIA, but also has occurred with subsequent doses. Angioedema reactions have occurred within hours of administration and in some instances had a delayed onset (i.e., days). 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 intravenous or subcutaneous ORENCIA should be stopped immediately and permanently discontinued, with appropriate therapy instituted.

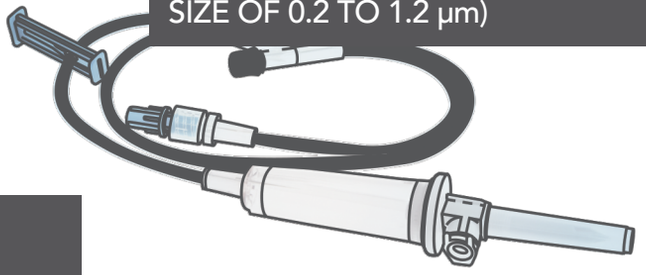
Please see Important Safety Information on page 11.

ORENCIA® (abatacept)
Injection for Intravenous Use
Injection for Subcutaneous Use

INFUSION SUPPLIES

To complete an infusion, you'll need:

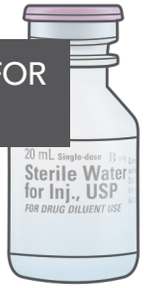
2, 3, OR 4 VIALS OF ORENCIA® (abatacept) IV BASED ON PATIENT WEIGHT



STERILE, NONPYROGENIC, LOW-PROTEIN–BINDING FILTER (PORE SIZE OF 0.2 TO 1.2 µm)

SILICONE-FREE DISPOSABLE SYRINGE

100-mL INFUSION BAG OR BOTTLE OF 0.9% SODIUM CHLORIDE INJECTION, USP



STERILE WATER FOR INJECTION, USP

18- TO 21-GAUGE NEEDLES

ALCOHOL SWABS

SELECTED IMPORTANT SAFETY INFORMATION

Infections: Serious infections, including sepsis and pneumonia, were reported in 3% and 1.9% of RA patients treated with intravenous ORENCIA and placebo, respectively. 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.

Please see Important Safety Information on page 11.

ORENCIA® (abatacept)
Injection for Intravenous Use
Injection for Subcutaneous Use

RECONSTITUTION

Follow these steps to reconstitute ORENCIA® (abatacept) IV using aseptic technique

WITHDRAW

- Use only the silicone-free* disposable syringe and an 18- to 21-gauge needle to withdraw 10 mL of Sterile Water for Injection, USP

WIPE

- Use the vial only if the vacuum is present. Remove the flip top of the ORENCIA IV vial and wipe the rubber stopper with an alcohol swab

INJECT

- Insert the syringe of Sterile Water for Injection, USP through the center of the rubber stopper. Direct the stream of liquid to the inside wall of the vial, injecting all 10 mL

ROTATE

- Gently swirl the vial to minimize foam formation, until the contents are completely dissolved

⚠ DO NOT SHAKE

VENT

- Vent the vial with the needle to dissipate any foam. Only use solution that appears clear and colorless to pale yellow. Discard solution if opaque particles, discoloration, or other foreign particles are present. Repeat these steps if 2, 3, or 4 vials are needed for a dose (see Page 3).

* If the ORENCIA lyophilized powder is accidentally reconstituted using a siliconized syringe, the solution may develop a few translucent particles (discard any solutions prepared using siliconized syringes).

If the silicone-free disposable syringe is dropped or becomes contaminated, use a new silicone-free disposable syringe.

SELECTED IMPORTANT SAFETY INFORMATION

Immunizations: Prior to initiating ORENCIA in adult patients, update vaccinations in accordance with current vaccination guidelines. ORENCIA-treated patients may receive current non-live vaccines. Live vaccines should not be given concurrently with ORENCIA or within 3 months after discontinuation. ORENCIA may blunt the effectiveness of some immunizations. In addition, it is unknown if the immune response of an infant who was exposed in utero to abatacept and subsequently administered a live vaccine is impacted. Risks and benefits should be considered prior to vaccinating such infants.

ORENCIA® (abatacept)
Injection for Intravenous Use
Injection for Subcutaneous Use

Please see Important Safety Information on page 11.

DILUTION

Using the same silicone-free syringe used for reconstitution, remove a volume of 0.9% Sodium Chloride Injection, USP, from a 100-mL infusion bag or bottle equal to the volume of the reconstituted ORENCIA solution required for the patient's dose:

2 VIALS: REMOVE 20 mL

3 VIALS: REMOVE 30 mL

4 VIALS: REMOVE 40 mL

- Use the same syringe to slowly add the reconstituted ORENCIA® (abatacept) IV to the infusion bag or bottle

- Complete the dilution by gently mixing the contents

DO NOT SHAKE THE BAG OR BOTTLE. IMMEDIATELY DISCARD ANY UNUSED PORTION IN THE VIAL.

REMEMBER TO ONLY USE THE SILICONE-FREE DISPOSABLE SYRINGE PROVIDED WITH EACH VIAL OF ORENCIA

SELECTED IMPORTANT SAFETY INFORMATION

Increased Risk of Adverse Reactions When Used in Patients with Chronic Obstructive Pulmonary Disease (COPD): In Study V, adult COPD patients treated with ORENCIA for RA developed adverse reactions more frequently than those treated with placebo, including COPD exacerbations, cough, rhonchi, and dyspnea. In the study, 97% of COPD patients treated with ORENCIA developed adverse events versus 88% treated with placebo. Respiratory disorders occurred more frequently in patients treated with ORENCIA compared to those on placebo (43% vs 24%, respectively), including COPD exacerbation, 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 COPD should be undertaken with caution, and such patients monitored for worsening of their respiratory status.

Please see Important Safety Information on page 11.

ORENCIA® (abatacept)
Injection for Intravenous Use
Injection for Subcutaneous Use

ADMINISTRATION

Prior to administration, visually inspect the ORENCIA diluted solution for particulate matter and discoloration. Discard the diluted solution if any particulate matter or discoloration is observed.

Administer the entire diluted ORENCIA solution over a period of 30 minutes with an infusion set and a *sterile, nonpyrogenic, low-protein–binding filter* (pore size of 0.2 to 1.2 µm).

Must complete the infusion of the diluted ORENCIA solution within 24 hours of reconstitution of the ORENCIA vials.

Do not infuse ORENCIA concomitantly in the same intravenous line with other agents. No physical or biochemical compatibility studies have been conducted to evaluate the coadministration of ORENCIA with other drugs.

SELECTED IMPORTANT SAFETY INFORMATION

Immunosuppression: In clinical trials in adult RA patients, a higher rate of infections was seen in ORENCIA-treated patients compared to placebo-treated patients. The impact of treatment with ORENCIA on the development and course of malignancies is not fully understood. There have been reports of malignancies, including skin cancer in patients receiving ORENCIA. Periodic skin examinations are recommended for all ORENCIA-treated patients, particularly those with risk factors for skin cancer.

Please see Important Safety Information on page 11.

ORENCIA®
(abatacept)
Injection for Intravenous Use
Injection for Subcutaneous Use

PATIENT INFORMATION AND FAQs

Before starting an ORENCIA® (abatacept) IV infusion, be prepared to counsel patients through the process, and ask if they have any questions before you begin. Provided below and on the following page are some infusion guidelines and potential questions patients may ask.

Discussing patient health

For first-time infusion patients: Check full medical history and conduct appropriate tests before the infusion

For all patients:

CHECK Check vital signs before and after infusion

ASK Ask about any recent health changes

ALERT Alert patients with diabetes that on the day of their infusion they may get a false high blood sugar reading on test strips with glucose dehydrogenase pyrroloquinoline quinone (GDH-PQQ)

REMIND Remind patients to call their healthcare provider if they feel sick or experience signs of infection including:

- ☐ Fever
- ☐ Feeling tired
- ☐ Cough
- ☐ Flu-like symptoms
- ☐ Warm, red, or painful skin

SELECTED IMPORTANT SAFETY INFORMATION

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 pyrroloquinoline quinone (GDH-PQQ). Consider using monitors and advising patients to use monitors that do not react with maltose, such as those based on glucose dehydrogenase nicotine 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.

Please see Important Safety Information on page 11.

ORENCIA® (abatacept)
Injection for Intravenous Use
Injection for Subcutaneous Use

PATIENT INFORMATION AND FAQs

Preparing an answer

Q HOW LONG WILL AN ORENCIA® (abatacept) IV INFUSION TAKE?

A Patients should plan to be at the infusion center for about an hour, but the actual infusion should only take 30 minutes.

Q WHAT WILL THE INFUSION FEEL LIKE?

A Patients should expect a small pinch when the needle is inserted. Advise them to alert a nurse if any discomfort continues during the infusion.

Q WHAT ARE POSSIBLE SIGNS AND SYMPTOMS OF AN INFUSION REACTION?

A An allergic reaction can happen. Patients should contact their healthcare provider immediately if they experience trouble breathing, hives, and/or swollen face, eyelids, lips, or tongue.

Q HOW OFTEN WILL I GET INFUSIONS?

A During the first month of treatment, patients will receive 3 infusions. After the first infusion, they will receive the second at week 2 and the third at week 4. After that, they will only have to receive infusions every 4 weeks.

SELECTED IMPORTANT SAFETY INFORMATION

Pregnancy: There are no adequate and well-controlled studies of ORENCIA use in pregnant women and the data with ORENCIA use in pregnant women are insufficient to inform on drug-associated risk. A pregnancy registry has been established to monitor pregnancy outcomes in women exposed to ORENCIA during pregnancy. Healthcare professionals are encouraged to register patients by calling 1-877-311-8972.

Lactation: There is no information regarding the presence of abatacept in human milk, the effects on the breastfed infant, or the effects on milk production. However, abatacept was present in the milk of lactating rats dosed with abatacept.

ORENCIA® (abatacept)
Injection for Intravenous Use
Injection for Subcutaneous Use

Please see Important Safety Information on page 11.

THANK YOU FOR USING THE ORENCIA® (abatacept) IV DOSAGE AND ADMINISTRATION GUIDE

If you have any questions about this material or would like to know more about ORENCIA support services, please call 1-800-ORENCIA or visit www.ORENCIAHCP.com

FOR MORE INFORMATION ON ORENCIA DOSING AND ADMINISTRATION, VISIT **WWW.ORENCIAHCP.COM** TO VIEW THE ORENCIA INFUSION VIDEO.

SELECTED IMPORTANT SAFETY INFORMATION

Most Serious Adverse Reactions: In controlled clinical trials, adult RA patients experienced 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 RA 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.

Please see Important Safety Information on page 11.

ORENCIA® (abatacept)
Injection for Intravenous Use
Injection for Subcutaneous Use

IMPORTANT SAFETY INFORMATION for ORENCIA® (abatacept)

Increased Risk of Infection with Concomitant Use with TNF Antagonists, Other Biologic RA/PsA Therapy, or JAK Inhibitors: Concurrent therapy with ORENCIA and a TNF antagonist is not recommended. In controlled clinical trials, adult RA patients receiving concomitant intravenous ORENCIA and TNF antagonist therapy experienced more infections (63% vs 43%) and serious infections (4.4% vs 0.8%) compared to patients treated with only TNF antagonists, without an important enhancement of efficacy. Additionally, concomitant use of ORENCIA with other biologic RA/PsA therapy or JAK inhibitors is not recommended.

Hypersensitivity Reactions: There were 2 cases (<0.1%; n=2688) of anaphylaxis reactions in clinical trials with adult RA patients treated with intravenous ORENCIA. Other reactions potentially associated with drug hypersensitivity, such as hypotension, urticaria, and dyspnea, each occurred in <0.9% of patients. In postmarketing experience, fatal anaphylaxis following the first infusion of ORENCIA and life-threatening cases of angioedema have been reported. Angioedema has occurred as early as after the first dose of ORENCIA, but also has occurred with subsequent doses. Angioedema reactions have occurred within hours of administration and in some instances had a delayed onset (i.e., days). 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 intravenous or subcutaneous ORENCIA should be stopped immediately and permanently discontinued, with appropriate therapy instituted.

Infections: Serious infections, including sepsis and pneumonia, were reported in 3% and 1.9% of RA patients treated with intravenous ORENCIA and placebo, respectively. 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: Prior to initiating ORENCIA in adult patients, update vaccinations in accordance with current vaccination guidelines. ORENCIA-treated patients may receive current non-live vaccines. Live vaccines should not be given concurrently with ORENCIA or within 3 months after discontinuation. ORENCIA may blunt the effectiveness of some immunizations. In addition, it is unknown if the immune response of an infant who was exposed *in utero* to abatacept and subsequently administered a live vaccine is impacted. Risks and benefits should be considered prior to vaccinating such infants.

Increased Risk of Adverse Reactions When Used in Patients with Chronic Obstructive Pulmonary Disease (COPD): In Study V, adult COPD patients treated with ORENCIA for RA developed adverse reactions more frequently than those treated with placebo, including COPD exacerbations, cough, rhonchi, and dyspnea. In the study, 97% of COPD patients treated with ORENCIA developed adverse events versus 88% treated with placebo. Respiratory disorders occurred more frequently in patients treated with ORENCIA compared to those on placebo (43% vs 24%, respectively), including COPD exacerbation, 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 COPD should be undertaken with caution, and such patients monitored for worsening of their respiratory status.

Immunosuppression: In clinical trials in adult RA patients, a higher rate of infections was seen in ORENCIA-treated patients compared to placebo-treated patients. The impact of treatment with ORENCIA on the development and course of malignancies is not fully understood. There have been reports of malignancies, including skin cancer in patients receiving ORENCIA. Periodic skin examinations are recommended for all ORENCIA-treated patients, particularly those with risk factors for skin cancer.

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 pyrroloquinoline quinone (GDH-PQQ). Consider using monitors and advising patients to use monitors that do not react with maltose, such as those based on glucose dehydrogenase nicotine 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.

Pregnancy: There are no adequate and well-controlled studies of ORENCIA use in pregnant women and the data with ORENCIA use in pregnant women are insufficient to inform on drug-associated risk. A pregnancy registry has been established to monitor pregnancy outcomes in women exposed to ORENCIA during pregnancy. Healthcare professionals are encouraged to register patients by calling 1-877-311-8972.

Lactation: There is no information regarding the presence of abatacept in human milk, the effects on the breastfed infant, or the effects on milk production. However, abatacept was present in the milk of lactating rats dosed with abatacept.

Most Serious Adverse Reactions: In controlled clinical trials, adult RA patients experienced 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 RA 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.

Please click here for Full Prescribing Information.

Reference: ORENCIA [package insert]. Princeton, NJ: Bristol-Myers Squibb Company.

Bristol Myers Squibb®

427-US-2400033 02/24

ORENCIA®
(abatacept)
Injection for Intravenous Use
Injection for Subcutaneous Use