INFUSING ORENCIA® (abatacept) IV

Your go-to guide for preparing and administering an ORENCIA® (abatacept) Intravenous (IV) infusion

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.

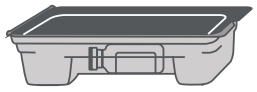
Please see additional Important Safety Information on page 10.

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

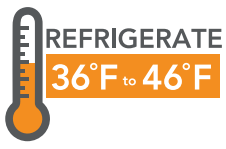
GENERAL ADMINISTRATION

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

Concomitant Use with TNF Antagonists: Concurrent therapy with ORENCIA and a TNF antagonist 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.

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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: Anaphylaxis or anaphylactoid reactions can occur during or after an infusion and can be life-threatening. There were 2 cases (<0.1%; n=2688) of anaphylaxis or anaphylactoid 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, 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.

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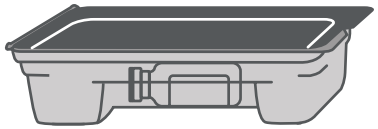
INFUSION SUPPLIES

A look at the infusion kit:



- 1 vial of ORENCIA® (abatacept)
- 1 silicone-free disposable syringe
- 1 full US Prescribing Information

SELECTED IMPORTANT SAFETY INFORMATION

Immunizations: Live vaccines should not be given concurrently with ORENCIA or within 3 months of its discontinuation. The efficacy of vaccination in patients receiving ORENCIA is not known. ORENCIA may blunt the effectiveness of some immunizations.

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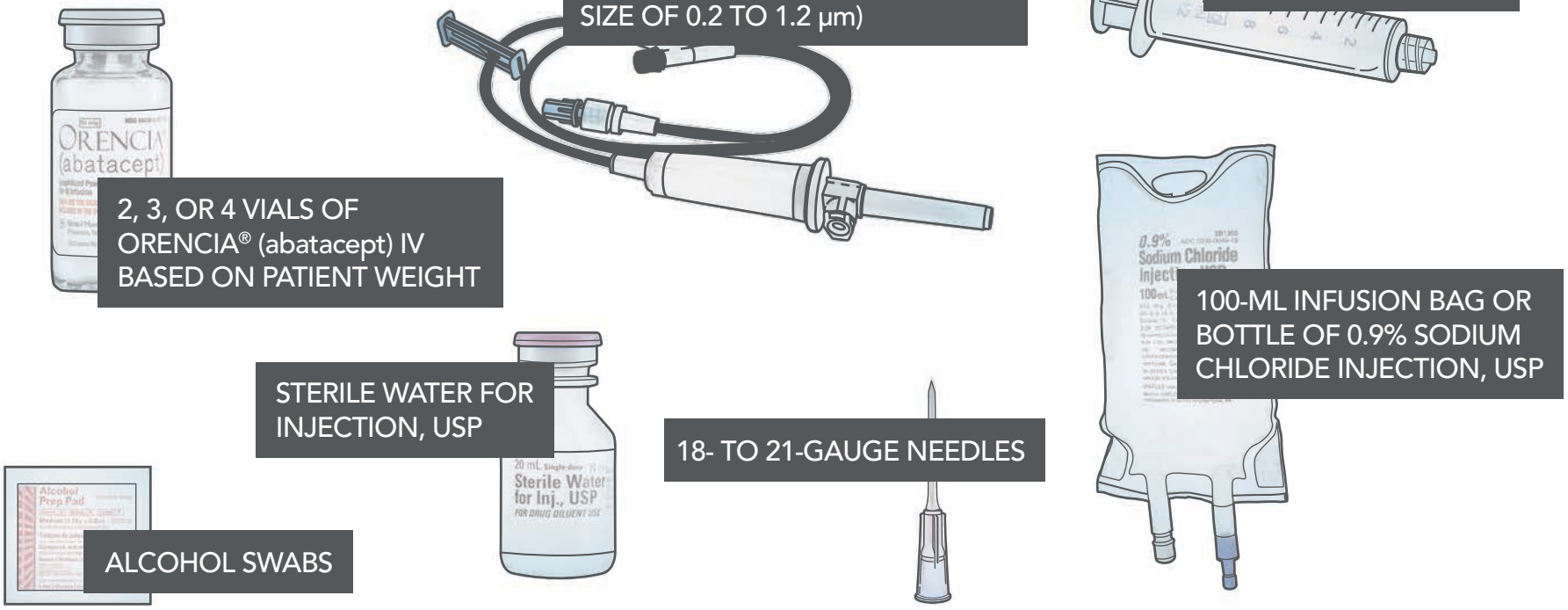
INFUSION SUPPLIES

To complete an infusion you'll need:



SELECTED IMPORTANT SAFETY INFORMATION

Use in Patients with Chronic Obstructive Pulmonary Disease (COPD): Adult 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 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 RA and COPD should be undertaken with caution, and such patients monitored for worsening of their respiratory status.

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RECONSTITUTION

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

WITHDRAW

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

WIPE

- 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 side of the vial, injecting all 10 mL

ROTATE

- Rotate the vial gently in a swirling motion, 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 or discoloration is present

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.

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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 reconstitution by gently mixing the contents

  DO NOT SHAKE THE BAG OR BOTTLE

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

SELECTED IMPORTANT SAFETY INFORMATION

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.

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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.

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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, swollen face, eyelids, lips, or tongue.

Q HOW LONG DOES ORENCIA TAKE TO WORK?

A Patients new to biologic therapy could see a response in as little as 15 days or up to 3 months. Response in patients previously treated with a biologic may be seen within 3 to 6 months.

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

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.

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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 have not been studied in patients under 18 years of age.

Click here for Full US Prescribing Information

Reference: ORENCIA® (abatacept) [package insert]. Princeton, NJ: Bristol-Myers Squibb.

Bristol-Myers Squibb

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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.ORENCIA.com/HCP

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

SELECTED IMPORTANT SAFETY INFORMATION

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