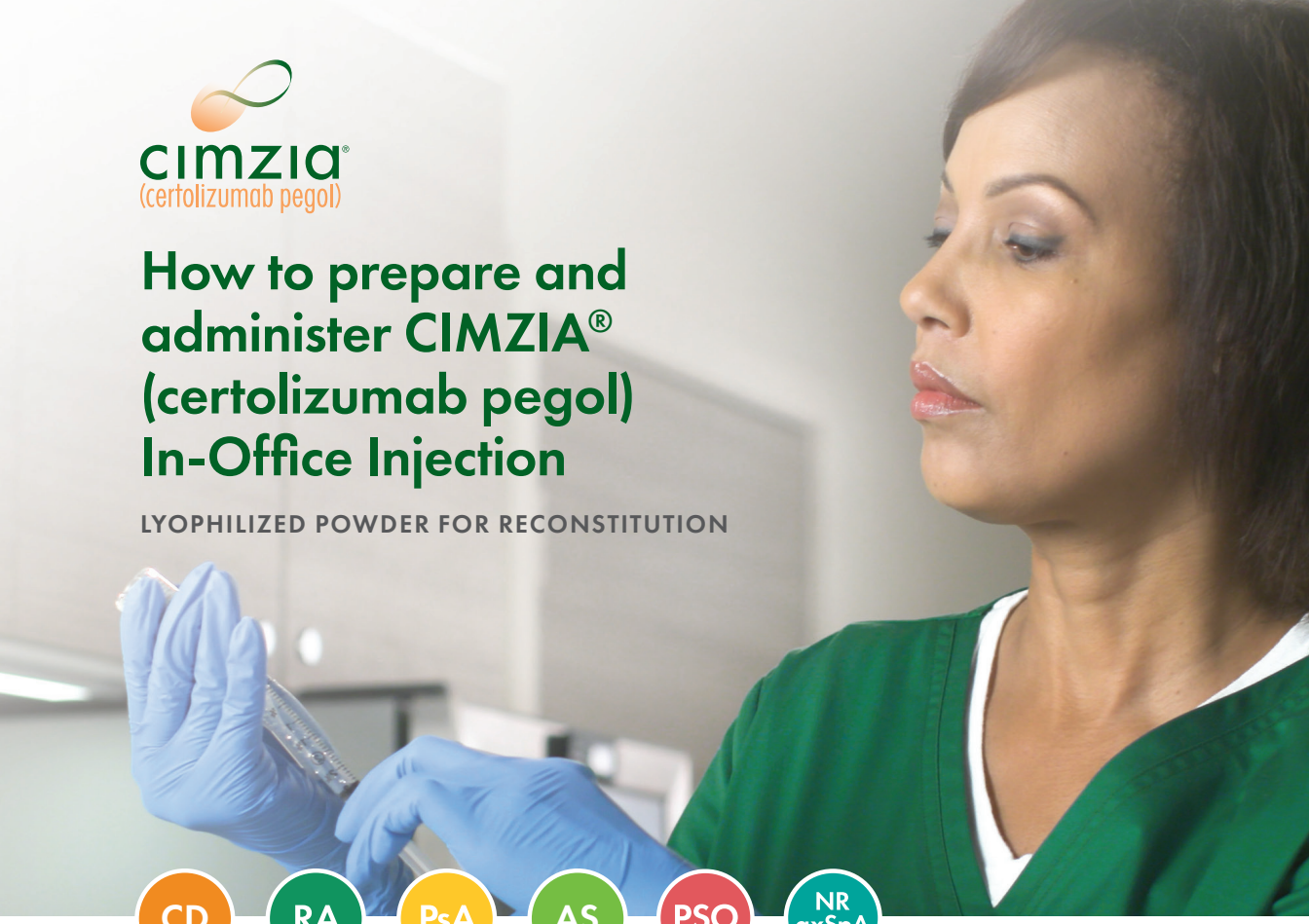
CIMZIA®
(certolizumab pegol)

How to prepare and administer CIMZIA® (certolizumab pegol) In-Office Injection

LYOPHILIZED POWDER FOR RECONSTITUTION



CD RA PsA AS PSO NR axSpA

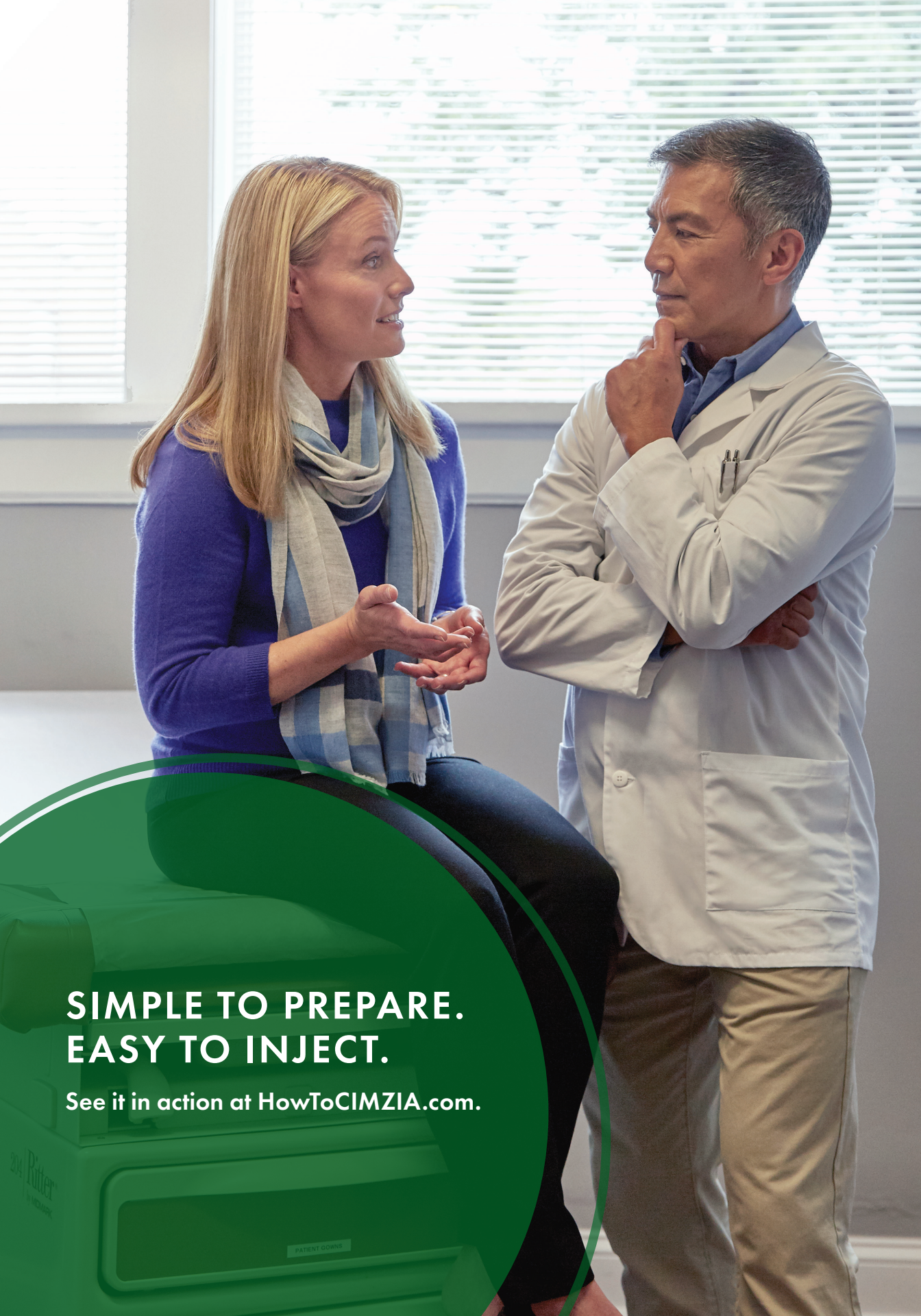
Indications

- CIMZIA is indicated for reducing signs and symptoms of Crohn's disease (CD) and maintaining clinical response in adults with moderately to severely active disease who have had an inadequate response to conventional therapy
- CIMZIA is indicated for the treatment of adults with moderately to severely active rheumatoid arthritis (RA)
- CIMZIA is indicated for the treatment of adult patients with active psoriatic arthritis (PsA)
- CIMZIA is indicated for the treatment of adult patients with active ankylosing spondylitis (AS)
- CIMZIA is indicated for the treatment of adults with moderate-to-severe plaque psoriasis (PSO) who are candidates for systemic therapy or phototherapy
- CIMZIA is indicated for the treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

Important Safety Information

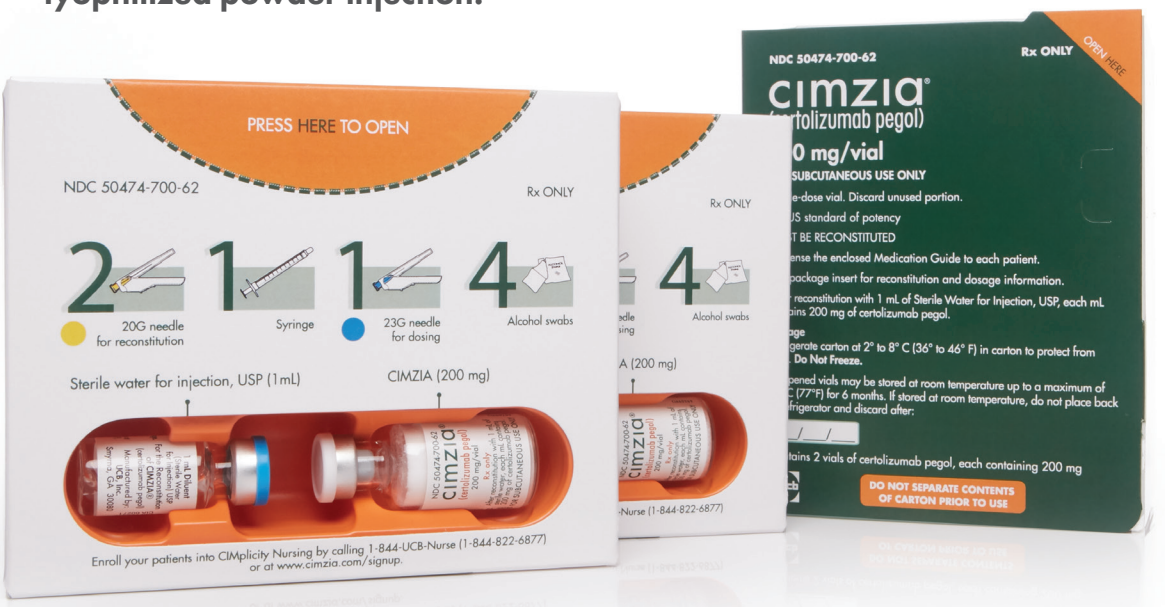
Serious and sometimes fatal side effects have been reported with CIMZIA, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens (such as Legionella or Listeria). Patients should be closely monitored for the signs and symptoms of infection during and after treatment with CIMZIA. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which CIMZIA is a member. CIMZIA is not indicated for use in pediatric patients.

Please see additional Important Safety Information on pages 14-15. Please refer to the full Prescribing Information provided by the UCB representative, and visit CIMZIAhcp.com.


SIMPLE TO PREPARE.
EASY TO INJECT.
See it in action at HowToCIMZIA.com.

PACKAGING

The CIMZIA In-Office Injection kit has two inner cartons—**each containing everything you'll need to prepare one 200 mg lyophilized powder injection.**



Each carton contains:

- **1** vial of CIMZIA
- **1** vial of sterilized water for injection
- **1** single-dose plastic syringe
- **4** alcohol swabs
- **2** reconstitution safety needles
- **1** dosing safety needle

The lyophilized powder should be prepared and administered by a healthcare professional as prescribed.

The Instructions for Use are clearly printed on the inside panel of the packaging and the dosing appears on the back cover of each carton. Please refer to pages 6-7 or the Prescribing Information for complete dosing information. A Medication Guide is included and should be given to your patient.

Important Safety Information

Anaphylaxis or serious allergic reactions may occur. Some of these reactions occurred after the first administration of CIMZIA. Hypersensitivity reactions have been reported rarely following CIMZIA administration. The needle shield inside the removable cap of the CIMZIA prefilled syringe contains a derivative of natural rubber latex which may cause an allergic reaction in individuals sensitive to latex.

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STORAGE

CIMZIA® (certolizumab pegol) should arrive to your office via cold-chain refrigeration. You should not separate the contents of the injection kit prior to use. Do not freeze, and protect solution from light.

There are two options for storing the CIMZIA In-Office Injection kit. You should determine which method best suits your office needs.

OPTION ONE
REFRIGERATION

The first storage option is to keep CIMZIA refrigerated between 2-8°C or 36-46°F.

OPTION TWO
ROOM TEMPERATURE

The other option is to store unopened CIMZIA vials at room temperature, up to a maximum temperature of 25°C or 77°F.

⚠ Once CIMZIA is stored at room temperature, it cannot be returned to the refrigerator.

Please see Important Safety Information on pages 14-15. Please refer to the full Prescribing Information provided by the UCB representative, and visit CIMZIAhcp.com.

EXPIRATION DATES

REFRIGERATION

If CIMZIA is stored in the refrigerator, use the original expiration date printed on the box and on each CIMZIA vial.

ROOM TEMPERATURE

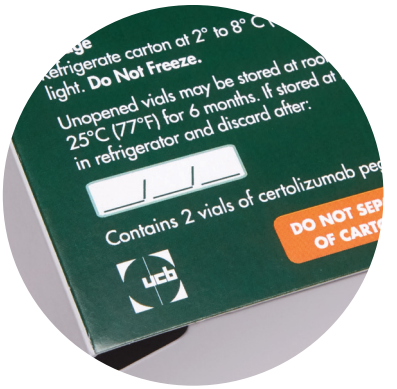
When storing at room temperature, the new expiration date becomes 6 months from the date of storage or from the date the injection kit was removed from the refrigerator and is **not to exceed the original expiration date**.

ROOM TEMPERATURE STORAGE EXAMPLE:

Storage date **Expiration date**

Write the new 6-month expiration date in the space provided on the injection kit and place the kit in a cabinet or wherever it is going to be stored.

Storing CIMZIA at room temperature ensures the drug is ready to be reconstituted, which may reduce injection preparation time as well as patient wait time.



⚠ **Do not freeze CIMZIA.** Do not use beyond the original expiration date printed on the box and on each CIMZIA vial.

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DOSING

Depending on the indication and your patient's prescribed dose, you will be reconstituting either one or two vials of CIMZIA® (certolizumab pegol)—**one vial for a 200 mg dose, or two vials for a 400 mg dose.** CIMZIA should be prepared and administered by a healthcare professional.

CD RA PsA AS NR axSpA LOADING DOSE[1*]

2 INJECTIONS	2 INJECTIONS	2 INJECTIONS
		
400 mg (2x200 mg/mL)	**400 mg** (2x200 mg/mL)	**400 mg** (2x200 mg/mL)
AT WEEK 0	**AT WEEK 2**	**AT WEEK 4**

CD MAINTENANCE DOSE[1*]

2 INJECTIONS

400 mg (2x200 mg/mL)
EVERY 4 WEEKS

RA PsA AS NR axSpA MAINTENANCE DOSE[1*]

1 INJECTION		2 INJECTIONS
	OR	
200 mg (1x200 mg/mL)		**400 mg** (2x200 mg/mL)
EVERY 2 WEEKS		**EVERY 4 WEEKS**

Important Safety Information

CIMZIA is contraindicated in patients with a history of hypersensitivity reaction to certolizumab pegol or to any of the excipients. Reactions have included angioedema, anaphylaxis, serum sickness, and urticaria.

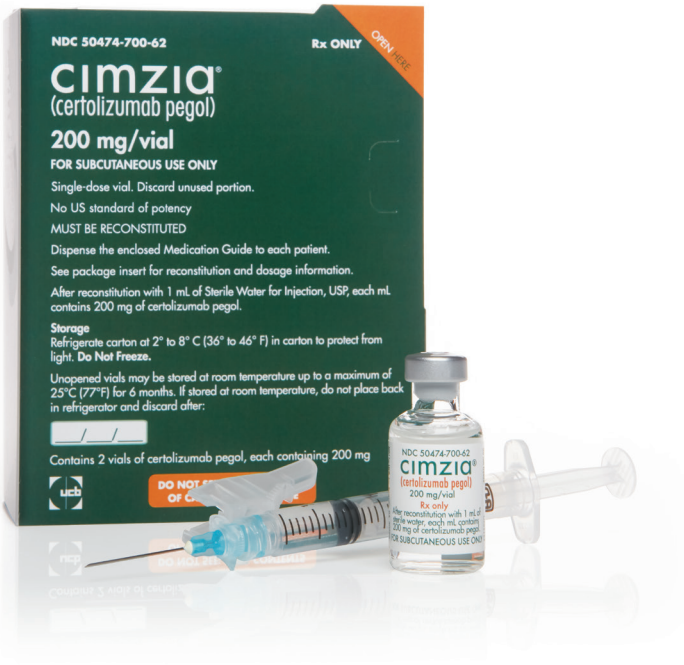
*For subcutaneous administration in abdomen or thigh. Please see full Prescribing Information for additional dosing and administration information.

PSO RECOMMENDED DOSE[1*]

2 INJECTIONS

400 mg
(2x200 mg/mL)

EVERY 2 WEEKS



The recommended dose of CIMZIA for PSO is 400 mg (given as two subcutaneous injections of 200 mg each) every other week.

OR

PSO ALTERNATE DOSING SCHEDULE[1*]

LOADING DOSE

2 INJECTIONS
400 mg
(2x200 mg/mL)
AT WEEKS 0, 2, 4

MAINTENANCE DOSE

1 INJECTION
200 mg
(1x200 mg/mL)
EVERY 2 WEEKS

For some patients (with body weight ≤90 kg), a dose of 400 mg (given as two subcutaneous injections of 200 mg each) initially and at weeks 2 and 4, followed by 200 mg every other week can be considered.

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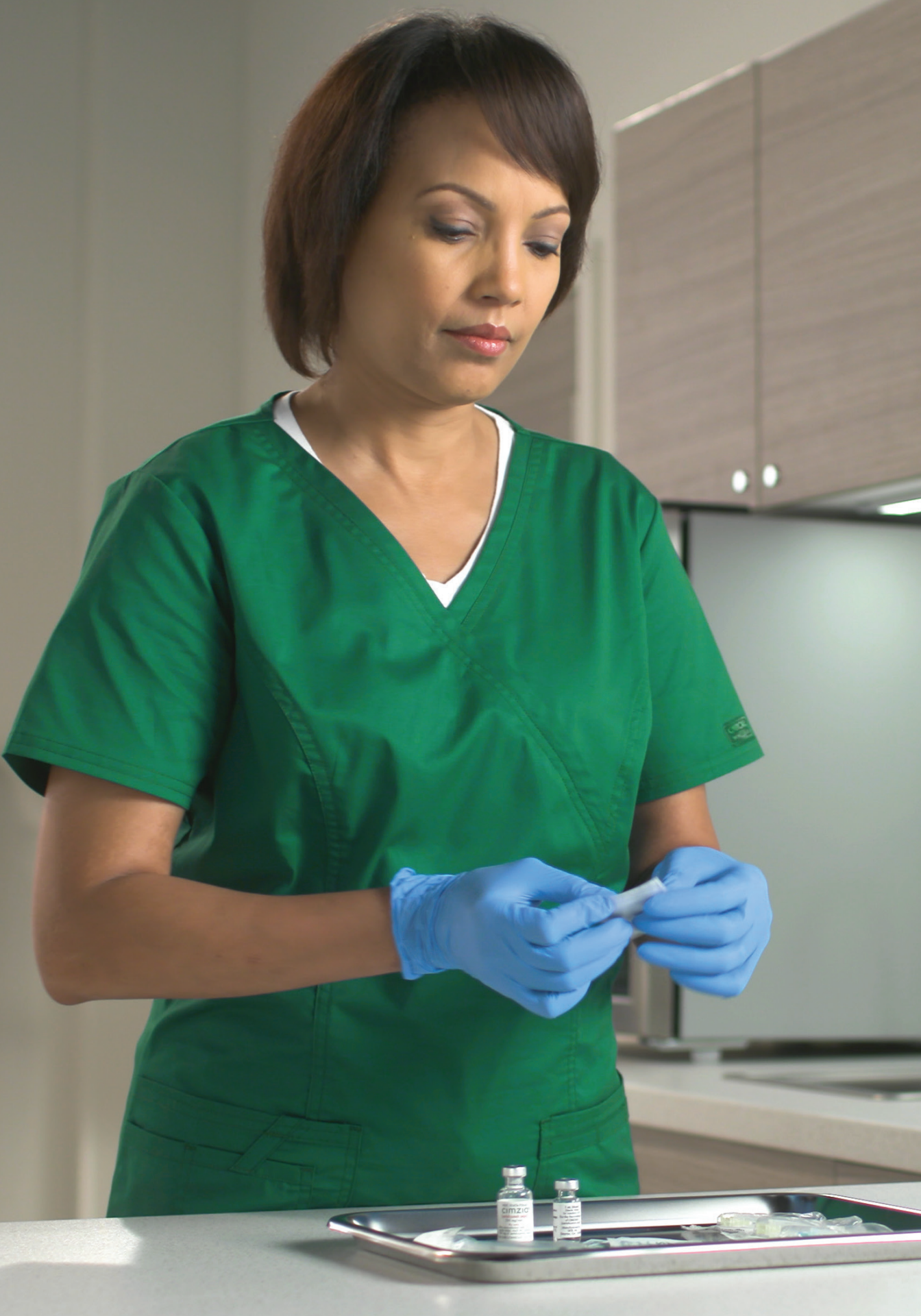
cimzia

PREPARATION

The process for preparing and injecting CIMZIA® (certolizumab pegol) lyophilized powder consists of three steps:

RECONSTITUTE | **WITHDRAW** | **INJECT**

Depending on the prescribed dose for your patient, you will open either one or both of the inner cartons from inside the injection kit.

REFRIGERATION

A refrigerated vial must be allowed to sit at room temperature for **30 minutes** before beginning the reconstitution process. Do not warm the vial in any other way.

ROOM TEMPERATURE

If CIMZIA is stored at room temperature, you can proceed with reconstituting.

Full preparation and administration instructions are available in the CIMZIA In-Office Injection kit on the inside panel, as well as in the full Prescribing Information.

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RECONSTITUTE

① STERILIZE

- Wash your hands and follow proper aseptic technique
- Use an alcohol swab to wipe the top of the CIMZIA® (certolizumab pegol) vial
- Use a second alcohol swab to wipe the top of the vial of sterile water, being careful not to touch the vial tops after wiping them

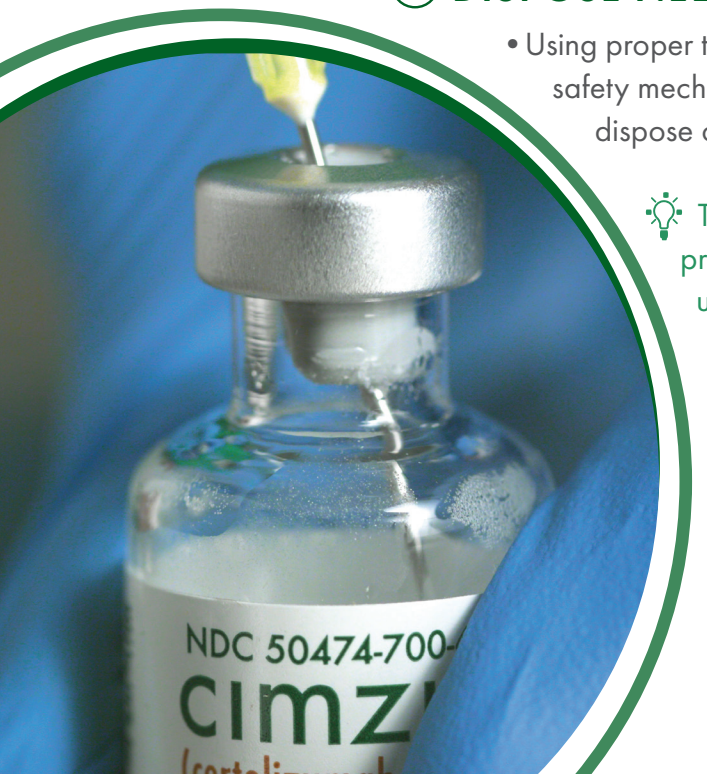
② BEGIN RECONSTITUTION

- Remove a new syringe and 20-gauge reconstitution safety needle from an inner carton
- Attach the safety needle to the syringe
- Withdraw 1 mL of sterile water and inject into one of the CIMZIA powder vials

Direct the injection at the vial wall, rather than directly into the CIMZIA powder.

③ DISPOSE NEEDLE

- Using proper technique, cap the needle using the safety mechanism, remove from the syringe and dispose of it in a sharps container



To ensure proper dosing, be sure to prepare the two injections separately, using only the materials provided for each.

4 MIX SOLUTION

- Gently swirl the vial of CIMZIA for 1 minute

⚠ Do not shake the CIMZIA vial. Swirl as gently as possible in order to avoid creating a foaming effect.

- Continue swirling every 5 minutes as long as non-dissolved particles are observed

Full reconstitution may take as long as 30 minutes, with only 10 minutes of hands-on time.

5 RECONSTITUTED SOLUTION

- The final reconstituted solution contains 200 mg/mL
- Solution should be clear to opalescent, colorless to pale yellow liquid, and essentially free of particulates
- When ready to inject, make sure the vial is at room temperature, but do not leave the solution at room temperature for more than 2 hours total prior to administration

⚠ If you are not ready to inject CIMZIA, you can refrigerate the reconstituted solution in the vials for up to 24 hours prior to injection. The solution must be stored between 2-8°C or 36-46°F. **Do not freeze.**

Full preparation and administration instructions are available in the CIMZIA In-Office Injection kit on the inside panel, as well as in the full Prescribing Information.

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WITHDRAW

PREPARE TO WITHDRAW

1. Using proper aseptic technique, pick up the syringe you had set aside earlier, attach a new 20-gauge safety needle provided in the kit, and remove the cap.
2. **Draw in 3 mL of air,** and inject it into the CIMZIA® (certolizumab pegol) vial.
3. Withdraw all of the reconstituted solution in the syringe so that it contains 1 mL of the CIMZIA 200 mg solution.
4. Cap the needle using the safety mechanism, remove the needle from the syringe, and dispose of it appropriately.
5. Attach the 23-gauge dosing safety needle for administration to the syringe and lay it on a clean, flat surface.

INJECT

PROPER INJECTION TECHNIQUE

1. Use an alcohol swab to sterilize the injection area. Do not touch the area again until you're ready to inject.
2. Holding the syringe in one hand, use the other hand to gently pinch a fold of skin.
3. Inject the full contents of the syringe subcutaneously into the previously cleaned injection site.
4. Initiate the safety mechanism of the needle, and dispose of the needle and syringe appropriately.
5. Discard all other used kit contents.
6. For patients requiring a second CIMZIA injection, please follow the same steps as the first injection.

PROPER INJECTION SITES

CIMZIA can be injected in an area on the abdomen or thigh.

⚠ Injection sites should be rotated. Injections should not be given where the skin is tender, bruised, red, or hard.

WHEN A 400 MG DOSE IS NEEDED

Injections should be given as two subcutaneous injections of 200 mg each. Injections should occur at separate sites in the thigh or abdomen.

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Important Safety Information

Contraindications

CIMZIA (certolizumab pegol) is contraindicated in patients with a history of hypersensitivity reaction to certolizumab pegol or to any of the excipients. Reactions have included angioedema, anaphylaxis, serum sickness, and urticaria.

Serious Infections

Patients treated with CIMZIA are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue CIMZIA if a patient develops a serious infection or sepsis.

Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before CIMZIA use and during therapy. Initiate treatment for latent TB prior to CIMZIA use.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

Carefully consider the risks and benefits of treatment with CIMZIA prior to initiating therapy in the following patients: with chronic or recurrent infection; who have been exposed to TB; with a history of opportunistic infection; who resided in or traveled in regions where mycoses are endemic; with underlying conditions that may predispose them to infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with CIMZIA, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

- Do not start CIMZIA during an active infection, including localized infections.
- Patients older than 65 years, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants may be at greater risk of infection.
- If an infection develops, monitor carefully and initiate appropriate therapy.

Malignancy

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which CIMZIA is a member. CIMZIA is not indicated for use in pediatric patients.

- Consider the risks and benefits of CIMZIA treatment prior to initiating or continuing therapy in a patient with known malignancy.
- In clinical trials, more cases of malignancies were observed among CIMZIA-treated patients compared to control patients.
- In CIMZIA clinical trials, there was an approximately 2-fold higher rate of lymphoma than expected in the general U.S. population. Patients with rheumatoid arthritis, particularly those with highly active disease, are at a higher risk of lymphoma than the general population.
- Malignancies, some fatal, have been reported among children, adolescents, and young adults being treated with TNF blockers. Approximately half of the cases were lymphoma, while the rest were other types of malignancies, including rare types associated with immunosuppression and malignancies not usually seen in this patient population.

- Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including CIMZIA. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF blocker cases have occurred in patients with Crohn's disease or ulcerative colitis, and the majority were in adolescent and young adult males. Almost all of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNF blocker at or prior to diagnosis. Carefully assess the risks and benefits of treating with CIMZIA in these patient types.
- Cases of acute and chronic leukemia were reported with TNF blocker use.

Heart Failure

- Worsening and new onset congestive heart failure (CHF) have been reported with TNF blockers. Exercise caution and monitor carefully.

Hypersensitivity

- Angioedema, anaphylaxis, dyspnea, hypotension, rash, serum sickness, and urticaria have been reported following CIMZIA administration. If a serious allergic reaction occurs, stop CIMZIA and institute appropriate therapy. The needle shield inside the removable cap of the CIMZIA prefilled syringe contains a derivative of natural rubber latex which may cause an allergic reaction in individuals sensitive to latex.

Hepatitis B Virus Reactivation

- Use of TNF blockers, including CIMZIA, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases have been fatal.
- Test patients for HBV infection before initiating treatment with CIMZIA.
- Exercise caution in patients who are carriers of HBV and monitor them before and during CIMZIA treatment.
- Discontinue CIMZIA and begin antiviral therapy in patients who develop HBV reactivation. Exercise caution when resuming CIMZIA after HBV treatment.

Neurologic Reactions

- TNF blockers, including CIMZIA, have been associated with rare cases of new onset or exacerbation of central nervous system and peripheral demyelinating diseases, including multiple sclerosis, seizure disorder, optic neuritis, peripheral neuropathy, and Guillain-Barré syndrome.

Hematologic Reactions

- Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia has been infrequently reported with CIMZIA.
- Consider stopping CIMZIA if significant hematologic abnormalities occur.

Drug Interactions

- Do not use CIMZIA in combination with other biological DMARDS.

Autoimmunity

- Treatment with CIMZIA may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

Immunizations

- Patients on CIMZIA should not receive live or live-attenuated vaccines.

Adverse Reactions

- The most common adverse reactions in CIMZIA clinical trials (≥8%) were upper respiratory infections (18%), rash (9%), and urinary tract infections (8%).

Reference
1. CIMZIA® [prescribing information], Smyrna, GA: UCB, Inc.; 2019.

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See how it all comes together at

HowToCIMZIA.com

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Additional questions, contact: