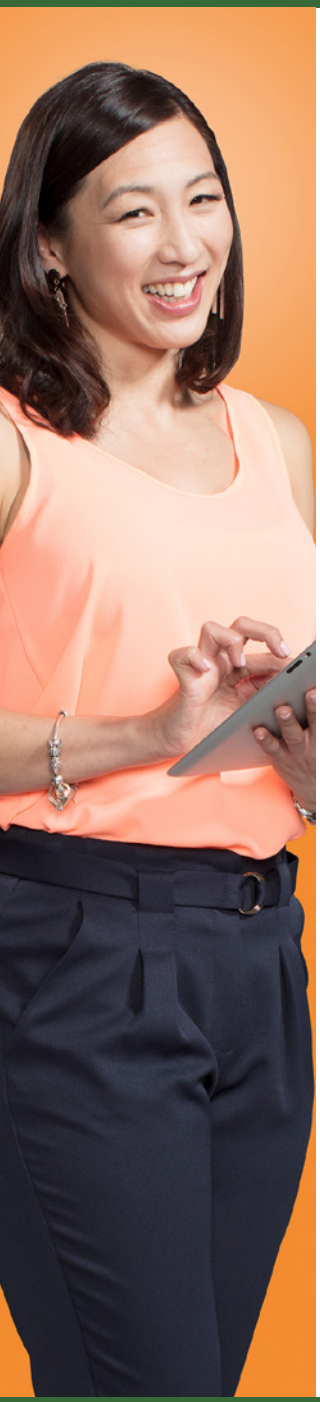
# Your CIMZIA® treatment guide

CIMZIA®
(certolizumab pegol)



# Support at hand

Together, you and your Rheumatologist have decided that CIMZIA® is appropriate for you.

PrCIMZIA® (certolizumab pegol) is a medication used to treat adults with:

- moderate to severe rheumatoid arthritis (RA)
- psoriatic arthritis (PsA)
- ankylosing spondylitis (AS)

This booklet is designed to be your personal treatment guide to help answer any questions you may have about your new treatment.
Remember, the more you know, the more equipped you will be to play an active role with your healthcare team.

**Keep in mind that this booklet is not meant to substitute any guidance, advice or help provided by your Rheumatologist.**

**CIMZIASolutions® is a patient support program that can help answer your questions. This program provides a wide range of services, including toll-free telephone support and providing tips to manage your condition. If you have any questions about CIMZIA®, talk to your Rheumatologist, Nurse Case Manager or call the CIMZIASolutions® Patient Support Hotline at:**

**1-800-908-5555**

**The hotline is available 8 am to 8 pm, EST, 5 days a week, Monday–Friday.**

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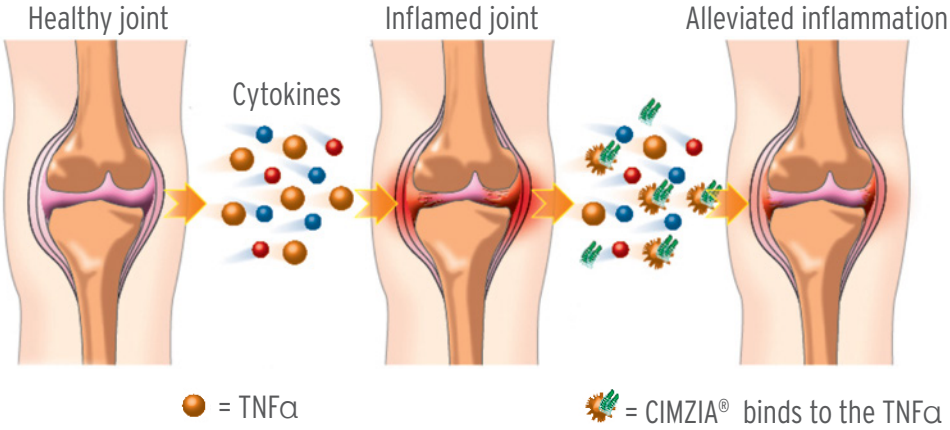
# What is CIMZIA®?

CIMZIA® is a medication used to treat moderate or severe rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis.

The active ingredient of CIMZIA® is called certolizumab pegol, a humanized antibody.



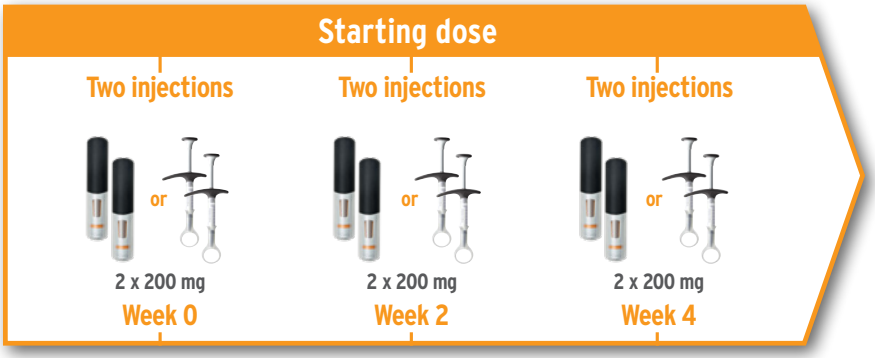

Antibodies are proteins that identify other proteins and bind to them. People with RA, PsA or AS usually have too much of a protein called tumour necrosis factor alpha (TNFα) in their bodies, which can cause painful and swollen joints. CIMZIA® works by binding itself to TNFα in order to reduce the amount of TNFα in the body back to normal levels, thus alleviating the inflammation.

# How often do I need to take CIMZIA®?

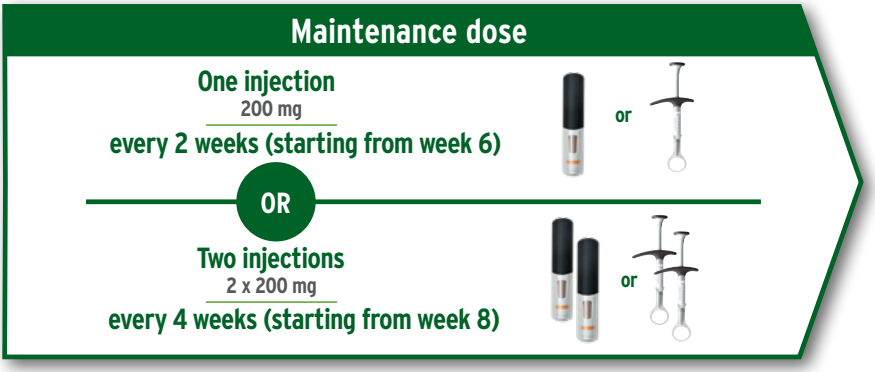
CIMZIA® is given by an injection under the skin (called a subcutaneous injection).

When you are first prescribed CIMZIA®, your physician will instruct you to take a **starting dose** of 400 mg of CIMZIA® at **weeks 0, 2, and 4**.

This means that you will take **2 injections** in one day as follows:




Subsequent doses (called maintenance doses) can be taken as follows:




**Be sure to use CIMZIA® exactly as prescribed by your Rheumatologist.**

# What does the CIMZIA® package contain?

The CIMZIA® medication package contains two prefilled autoinjectors or syringes (2 x 200 mg) and two alcohol wipes (additional packages are also available).

Administration instructions are given on page [11] of this booklet and are also available in the consumer information leaflet you received with your medication package.

Your Rheumatologist, their nurse or your Nurse Case Manager will show you how to inject CIMZIA® before doing it yourself. When you are taking CIMZIA® at home, you may want to have someone with you so they can support you while you take your injection. You can call your Rheumatologist or Nurse Case Manager if you have any questions about giving yourself an injection.

# CIMZIA®: Designed with you in mind

CIMZIA® autoinjector pen

CIMZIA® prefilled syringe

**Button-free injection**

**Wide, latex-free, non-slip grip**

**First click** signals injection initiation

**Second click** signals injection completion (after 15 seconds)

**Orange band** indicates device is ready to use

**Viewing window** enables you to monitor medication administration (turns orange upon injection completion)

**Retractable needle** locks and is hidden after injection

**Large thumb pad** makes it easier for you to push the plunger

**Over-sized plunger rod** provides stability

**Non-slip finger grip** allows you to hold the syringe steady using various grip positions

**Oval syringe barrel** helps prevent spinning between fingers

**Rounded finger loop** enables easy removal of needle cap

**Prefilled syringe designed for comfort and control in partnership with**
**Pen designed for comfort and ease-of-use in partnership with**

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# How do I store my medication?

CIMZIA® must be stored in a refrigerator at a temperature of 2°C to 8°C. The autoinjector and the syringes must be protected from freezing. When necessary, CIMZIA® may be stored at room temperature, up to 25°C, for a single period of a maximum 10 days with protection from light. At the end of this period CIMZIA® **must be used or discarded**.

Because CIMZIA® is sensitive to light, keep the autoinjector and syringes in their original packages.

## What do I do if I miss a dose?

If you forget to take your dose of CIMZIA® at your regularly scheduled time, do as follows:

- If your next scheduled dose is within 1 week, wait until your next scheduled dose
- If your next scheduled dose is 1 week or longer, inject the missed dose as soon as you become aware of it, and then follow with your next scheduled dose

**Be sure to take your medication exactly as prescribed. You should continue to use CIMZIA® as long as you and your Rheumatologist feel it is working for you. Talk to your Rheumatologist before discontinuing treatment with CIMZIA®.**

## Can I use other medications with CIMZIA®?

Tell your Rheumatologist about all the medications you are taking including prescription, non-prescription as well as any vitamin and herbal supplements.

Your Rheumatologist will tell you if you may take other medications or supplements while you are taking CIMZIA®.

**Keep a list of all medications you are taking to show your Rheumatologist and pharmacist each time you are prescribed a new medication**

## Can I use CIMZIA® while family planning, during pregnancy or breastfeeding?

The use of adequate contraception should be considered for women of childbearing potential, but the need for treatment should also be taken into account. Please speak to your Rheumatologist about CIMZIA® use when

family planning, during pregnancy or if you are breastfeeding. CIMZIA® should be used during pregnancy only if clearly needed. The use of CIMZIA® may be considered during breastfeeding.

## CIMZIA® and vaccinations

It is important to talk to your Rheumatologist if you have had or are scheduled to have any vaccinations. You should not receive certain (live) vaccines while taking CIMZIA®.

## What should I do when travelling?

When you are travelling, take only the amount of CIMZIA® you will need along with one extra dose. You should take the original prescription or a copy of it as well.

Pack your autoinjector or syringes in your carry-on luggage in their original packaging and use the cooler provided to you to carry them. Once at your destination, place the CIMZIA® packages in a cool place, such as the refrigerator of your hotel room. CIMZIA® must be stored in a refrigerator at a temperature of 2°C to 8°C. The autoinjector and the syringes must be protected from freezing. When necessary, CIMZIA® may be stored at room temperature up to 25°C, for a single period of a maximum 10 days with protection from light. At the end of this period CIMZIA® **must be used or discarded**. Because CIMZIA® is sensitive to light, keep the autoinjector and syringes in their original packages.

# Side effects

Like all medications, CIMZIA® can cause side effects.

The most common side effects reported include:

- Upper respiratory tract infections (such as flu, cold)
- Other infections including pneumonia, bronchopneumonia (a bronchitis) and herpes zoster (shingles)
- Fatigue
- Skin infections

Some people may experience a reaction at the site where the injection was given such as pain, redness, swelling, itching or bruising.

Tell your Rheumatologist if you experience any side effects, including any that are not listed here.

**For more information about side effects (including those less common, but serious), refer to the *Consumer Information Leaflet* that you received with the CIMZIA® medication package. Read this leaflet carefully before taking the first dose of CIMZIA®.**

# CIMZIA® autoinjector preparation and instructions

CIMZIA® is given by an injection under the skin which can be self-administered once you have received proper training from your Rheumatologist, their nurse or your Nurse Case Manager. You may also want to consider getting help from a family member or friend.

Do not attempt to self-inject until you are sure that you understand how to prepare and give the injection.

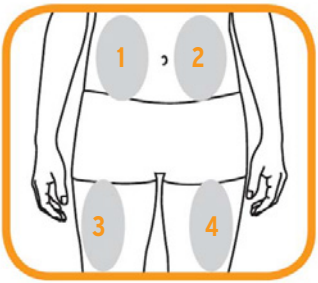
Instructions for self-injection are as follows:

## 1. Setting up

Prepare your injection:

- Wash your hands thoroughly
- Remove the CIMZIA® package from the refrigerator 30–45 minutes before the injection time to allow it to warm up at room temperature
- Remove the following items from the CIMZIA® package and set them up on a clean flat surface:
  - One prefilled autoinjector
  - One alcohol wipe
- **ONLY REMOVE** the cap of the device when you have thoroughly reviewed the detailed instructions in this brochure
- Look at the expiry date on the autoinjector and package
  - Do not use CIMZIA® after the expiry date which is stated on the package and autoinjector device
  - The expiry date refers to the last day of the month shown
- Allow CIMZIA® to reach room temperature to help minimize discomfort during the injection
  - This will take 30–45 minutes
  - Do not try to warm the autoinjector in any other way

## 2. Choosing and preparing an injection site




**1** = Stomach, right
**2** = Stomach, left
**3** = Upper thigh, right
**4** = Upper thigh, left

**Begin by:**

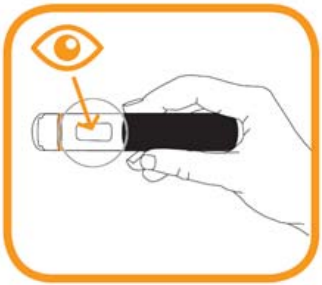
- Choosing a site on your thigh or stomach
  - Each new injection should be given on a separate site from the last injection site
  - Do not inject in an area where the skin is reddened, bruised or hard
  - Wipe the injection site with the enclosed alcohol wipe using a circular motion moving from the inside out
  - Do not touch the area again before injecting

## 3. Injection

The autoinjector is designed to work accurately and safely. However, if any of the following steps go wrong and/or if you feel unsure about the injection process, contact your doctor or pharmacist.

**Do not:**

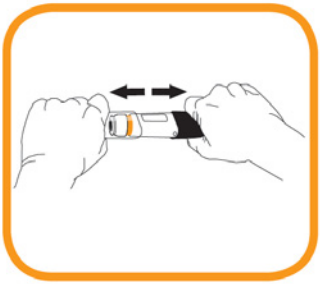
- Shake the autoinjector
- Use the autoinjector if the solution is discoloured, cloudy or if you can see particles in it
  - You can check the medication through the viewing window



You may see air bubbles – this is normal. There is no need to remove air bubbles before the injection. Injecting the solution subcutaneously with air bubbles is harmless.

**Steps to perform the injection:**

- Hold the autoinjector firmly with one hand around the black handle
- Grasp the clear cap with the other hand and pull it straight off
  - Do not twist the cap while removing it, as this could jam the internal mechanism



- Hold the autoinjector straight (at a 90 degree angle) against the skin that has been cleaned (the "injection site")

- Press the autoinjector firmly against the skin
  - The injection begins when a first "click" is heard and the orange band at the bottom of the autoinjector disappears

- Continue to hold the autoinjector firmly against the skin until a second "click" is heard and the viewing window turns orange
  - This can take up to 15 seconds
  - If the viewing window turns orange and you hear a second click, this means the injection is complete
  - If you feel unsure about the injection process, please contact your doctor or pharmacist
  - Do not try to repeat the injection without speaking to your doctor or pharmacist

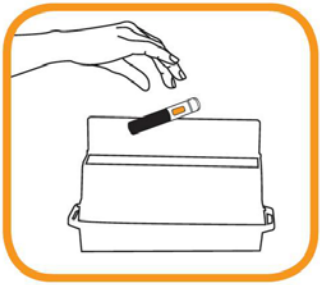
- The needle will automatically move back into the empty device
  - Do not try to touch the needle
- You can now remove the autoinjector by pulling the pen straight up carefully from the skin
- Use a piece of gauze to apply pressure over the injection site for a few seconds
  - Do not rub the injection site
  - You may cover the injection site with a small bandage if necessary

## 4. Throwing away supplies

Do not re-use the autoinjector. Do not replace the cap.

After the injection, immediately throw away the autoinjector in a special container as instructed by your doctor, nurse or pharmacist.

Be sure to keep the container out of the sight and reach of children.



# CIMZIA® pre-filled syringe preparation and instructions

CIMZIA® is given by an injection under the skin which can be self-administered once you have received proper training from your Rheumatologist, their nurse or your Nurse Case Manager. You may also want to consider getting help from a family member or friend.

Do not attempt to self-inject until you are sure that you understand how to prepare and give the injection.

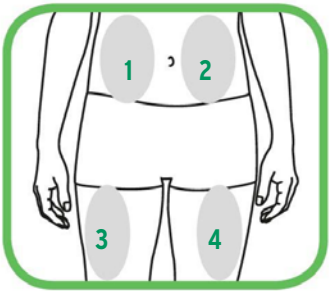
Instructions for self-injection are as follows:

## 1. Setting up

Prepare your injection:

- Wash your hands thoroughly
- Remove the CIMZIA® package from the refrigerator 30–45 minutes before the injection time to allow it to warm up at room temperature
- Remove the following items from the CIMZIA® package and set them up on a clean flat surface:
  - One prefilled syringe
  - One alcohol wipe
- **ONLY REMOVE** the cap of the device when you have thoroughly reviewed the detailed instructions in this brochure
- Look at the expiry date on the syringe and package
  - Do not use CIMZIA® after the expiry date which is stated on the package and syringe
  - The expiry date refers to the last day of the month shown
- Allow CIMZIA® to reach room temperature to help minimize discomfort during the injection
  - This will take 30–45 minutes
  - Do not try to warm the syringe in any other way

## 2. Choosing and preparing an injection site




**1** = Stomach, right
**2** = Stomach, left
**3** = Upper thigh, right
**4** = Upper thigh, left

**Begin by:**

- Choosing a site on your thigh or stomach
  - Each new injection should be given on a separate site from the last injection site
  - Do not inject in an area where the skin is reddened, bruised or hard
  - Wipe the injection site with the enclosed alcohol wipe using a circular motion moving from the inside out
  - Do not touch the area again before injecting

## 3. Injection

Check the medication in the body of the syringe.

**Do not:**

- Shake the syringe
- Use if the solution is discoloured, cloudy or if you can see particles in it

You may see air bubbles – this is normal. There is no need to remove air bubbles before the injection. Injecting the solution subcutaneously with air bubbles is harmless.

Remove the cap from the needle while being careful not to touch the needle or let the needle touch any surface. Do not bend the needle.

**Steps to perform the injection:**

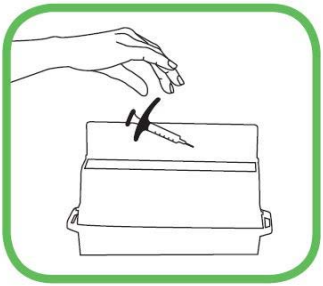
- Gently grasp the cleaned area of the skin with one hand and hold firmly
- With the other hand, hold the syringe at a 45 degree angle to the skin
- With one quick, short motion, push the needle all the way into the skin
- Release the skin with the first hand, keeping the syringe in position
- Push the plunger to inject solution
  - It can take up to 10 seconds to empty the syringe
- When the syringe is empty, carefully remove the needle from the skin at the same angle at which it was inserted
- Use a piece of gauze to apply pressure over the injection site for a few seconds
  - Do not rub the injection site
  - You may cover the injection site with a small adhesive bandage if necessary

## 4. Throwing away supplies

You should **not** re-use the syringe or re-cap the needle.

After the injection, immediately throw away the used syringe in a special container as instructed by your doctor, nurse or pharmacist.

Be sure to keep the container out of the sight and reach of children.



# Your treatment diary

This personal diary is designed to help you and your healthcare team keep track of how you are feeling during treatment with CIMZIA®.

There is also a section designated for note-taking. You can use this to write down questions you have for your Rheumatologist and any answers you receive.

Consider the following questions when you are filling out your diary and sharing with your Rheumatologist, their nurse or your Nurse Case Manager to help you get the most out of your treatment:

- How have your symptoms changed?
- Is there anything you can do now that you couldn't before treatment?
- How do you feel now compared to the last time you visited the Rheumatologist?
- How do you feel now compared to before you started treatment?
- Are you stiff in the mornings? If so, for how long?

You can also use this diary to help you keep track of your injection dates and sites. This will make it easier for you to remember where you injected last so that you regularly change the injection site.

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## Contact information

Rheumatologist name:

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Telephone no. :

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Nurse Case Manager name:

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Telephone no. :

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Pharmacist name:

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Telephone no. :

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**Other**

Name:

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Telephone no. :

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# CIMZIASolutions® program

CIMZIASolutions® was designed to support you throughout treatment with CIMZIA®. As part of the CIMZIASolutions® program, there are many services you can use to get the most out of your therapy.

## Answering your questions

At times, living with your condition can be difficult. It is often helpful to talk to someone about any questions or concerns you might have. CIMZIASolutions® is here to help!

**Option 1:** You can contact your Nurse Case Manager to help you manage your therapy and answer any questions you might have. Your Nurse Case Manager will provide you with a direct number to contact them.

Your Nurse Case Manager is available 9 am to 5 pm, local time, Monday to Friday.

**Option 2:** The CIMZIASolutions® Patient Support Hotline at 1-800-908-5555 is there for you. A registered nurse is available to take your call and answer any questions you might have about your CIMZIA® treatment.

The hotline is available 8 am to 8 pm, EST, 5 days a week, Monday to Friday.

If you have questions, just call your Nurse Case Manager or the toll-free CIMZIASolutions® Patient Support Hotline at: **1-800-908-5555.**

# CIMZIASolutions® services

## Your Nurse Case Manager

Your Nurse Case Manager is there to support you during your treatment journey with CIMZIA®. They will explain all of the services offered by the CIMZIASolutions® program. Together, you can find the services that work best for you.

## Prescription drug coverage

Obtaining drug coverage is important. Your Nurse Case Manager will help determine what kind of drug coverage you have. They will work to help you find the best drug coverage options for your CIMZIA® therapy.

## Financial assistance

Your CIMZIASolutions® Nurse Case Manager will find out if you are eligible for the CIMpay® financial assistance program.

## Pharmacy services

The CIMZIASolutions® patient program offers a variety of pharmacy services. Through the specialty pharmacy services offered by CIMZIASolutions®, you can choose to have your CIMZIA® delivered straight to your home. The specialty pharmacy also has equipment on hand to make sure CIMZIA® stays at the right temperature while it is on its way to you! If you have any questions, pharmacists from the specialty pharmacy can offer expert advice about CIMZIA® or any other medications you may be taking.

## Injection training

As part of CIMZIASoluions® services, arrangement can be made to have a registered nurse teach you how to inject CIMZIA®. For more information about how to inject CIMZIA®, see the step-by-step instructions in this booklet.

## Notes

## Notes

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CIMZIA®
(certolizumab pegol)