Package leaflet: Information for the user

Cimzia 200 mg solution for injection in dose-dispenser cartridge
certolizumab pegol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

Your physician will also give you a Patient Reminder Card, which contains important safety information of which you need to be aware before you are given Cimzia and during treatment with Cimzia. Keep this Patient Reminder Card with you.

1. What Cimzia is and what it is used for

Cimzia contains the active substance certolizumab pegol, a human antibody fragment. Antibodies are proteins that specifically recognise and bind to other proteins. Cimzia binds to a specific protein called tumour necrosis factor α (TNFα). Thereby this TNFα is blocked by Cimzia and this decreases inflammation diseases such as in rheumatoid arthritis, axial spondyloarthritis, psoriatic arthritis and psoriasis. Medicines that bind to TNFα are also called TNF blockers.

Cimzia is used in adults for the following inflammatory diseases:
- **rheumatoid arthritis,**
- **axial spondyloarthritis** (including ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis),
- **psoriatic arthritis,**
- **plaque psoriasis**

Rheumatoid arthritis
Cimzia is used to treat rheumatoid arthritis. Rheumatoid arthritis is an inflammatory disease of the joints. If you have moderate to severe active rheumatoid arthritis, you may first be given other medicines usually methotrexate. If you do not respond well enough to these medicines, you will be given Cimzia in combination with methotrexate to treat your rheumatoid arthritis. If your doctor determines that methotrexate is inappropriate, Cimzia can be given alone.

Cimzia in combination with methotrexate can also be used to treat severe, active and progressive rheumatoid arthritis without previous use of methotrexate or other medicines treatment.

Cimzia, which you will take in combination with methotrexate, is used to:
- reduce the signs and symptoms of your disease,
- slow down the damage to the cartilage and bone of the joints caused by the disease,
- improve your physical function and performance of daily tasks.

Ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis
Cimzia is used to treat severe active ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis (sometimes referred to as non-radiographic axial spondyloarthritis). These diseases are inflammatory diseases of the spine.

If you have ankylosing spondylitis or non-radiographic axial spondyloarthritis you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Cimzia to:
- reduce the signs and symptoms of your disease,
- improve your physical function and performance of daily tasks.

Psoriatic arthritis
Cimzia is used to treat active psoriatic arthritis. Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis. If you have active psoriatic arthritis you will first be given other medicines, usually methotrexate. If you do not respond well enough to these medicines, you will be given Cimzia in combination with methotrexate to:
- reduce the signs and symptoms of your disease,
- improve your physical function and performance of daily tasks.

If your doctor determines that methotrexate is inappropriate, Cimzia can be given alone.

Plaque psoriasis
Cimzia is used to treat moderate to severe plaque psoriasis. Plaque psoriasis is an inflammatory disease of the skin, and can also affect your scalp and nails.
Cimzia is used to reduce skin inflammation and other signs and symptoms of your disease.

2. What you need to know before you use Cimzia

Do NOT use Cimzia:
- If you are **ALLERGIC** (hypersensitive) to certolizumab pegol or any of the other ingredients of this medicine (listed in section 6)
- If you have a severe infection, including active **TUBERCULOSIS** (TB).
- If you have moderate to severe **HEART FAILURE**. Tell your doctor if you have had or have a serious heart condition.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Cimzia if any of the following applies to you:

Allergic reactions
- If you experience **ALLERGIC REACTIONS** such as chest tightness, wheezing, dizziness, swelling or rash, stop using Cimzia and contact your doctor **IMMEDIATELY**. Some of these reactions could occur after the first administration of Cimzia.
- If you have ever had an allergic reaction to latex.

Infections
- If you have had **RECURRENT or OPPORTUNISTIC INFECTIONS** or other conditions that increase the risk of infections (such as treatment with immunosuppressants, which are medicines that could reduce your ability to fight infections).
- If you have an infection or if you develop symptoms such as fever, wounds, tiredness or dental problems. You might get an infection more easily while you are being treated with Cimzia, including serious, or in rare cases, life-threatening infections.
- **TUBERCULOSIS (TB)** cases have been reported in patients treated with Cimzia, your doctor will check you for signs and symptoms of tuberculosis before starting Cimzia. This will include a thorough medical history, a chest X-ray and a tuberculin test. The conduct of these tests should be recorded on your Patient Reminder Card. If latent (inactive) tuberculosis is diagnosed, you might be required to receive appropriate anti tuberculosis medicines before starting Cimzia. In rare occasions tuberculosis can develop during therapy even if you have received preventive

treatment for tuberculosis. It is very important that you tell your doctor if you have ever had tuberculosis, or if you have been in close contact with someone who has had tuberculosis. If symptoms of tuberculosis (persistent cough, weight loss, listlessness, mild fever), or any other infection appear during or after therapy with Cimzia tell your doctor immediately.
- If you are at risk of or are a carrier of or have active **HEPATITIS B VIRUS (HBV)** infection, Cimzia may increase the risk of reactivation in people who carry this virus. If this occurs, you should stop using Cimzia. Your doctor should test you for HBV before starting Cimzia.

Heart failure
- If you have mild **HEART FAILURE** and you are being treated with Cimzia, your heart failure status must be closely monitored by your doctor. It is important to tell your doctor if you have had or have a serious heart condition. If you develop new or worsening symptoms of heart failure (e.g. shortness of breath or swelling of your feet), you must contact your doctor immediately. Your doctor may decide to stop treatment with Cimzia.

Cancer
- It is uncommon, but cases of certain types of **CANCER** have been reported in patients treated with Cimzia or other TNF blockers. People with more severe rheumatoid arthritis that have had the disease for a long time may have a higher than average risk of getting a kind of cancer that affects the lymph system, called lymphoma. If you take Cimzia, your risk of getting lymphoma or other cancers may increase. In addition, uncommon cases of non-melanoma skin cancer have been observed in patients taking Cimzia. If new skin lesions appear during or after therapy with Cimzia or existing skin lesions change appearance, tell your doctor.
- There have been cases of cancers, including unusual types, in children and teenage patients taking TNF blocking agents, which sometimes resulted in death (see further down “Children and adolescents”).

Other disorders
- Patients with chronic obstructive pulmonary disease (COPD), or who are heavy smokers, may be at increased risk for cancer with Cimzia treatment. If you have COPD or are a heavy smoker, you should discuss with your doctor whether treatment with a TNF blocker is appropriate for you.
- If you have a nervous system disorder, such as multiple sclerosis, your doctor will decide whether you should use Cimzia.
- In some patients the body may fail to produce enough of the blood cells that help your body fight infections or help you to stop bleeding. If you develop a fever that does not go away, bruise or bleed very easily or look very pale, call your doctor immediately. Your doctor may decide to stop treatment with Cimzia.
- It is uncommon, but symptoms of a disease called lupus (for example persistent rash, fever, joint pain and tiredness) may occur. If you experience these symptoms, contact your doctor. Your doctor may decide to stop treatment with Cimzia.

Vaccinations
- Talk to your doctor if you have had, or are due to have a vaccine. You should not receive certain (live) vaccines while using Cimzia.
- Certain vaccinations may cause infections. If you received Cimzia while you were pregnant, your baby may be at higher risk for getting such an infection for up to approximately five months after the last dose you received during pregnancy. It is important that you tell your baby's doctors and other health care professionals about your Cimza use so they can decide when your baby should receive any vaccine.

Operations or dental procedures
- Talk to your doctor if you are going to have any operations or dental procedures. Tell your surgeon or dentist performing the procedure that you are having treatment with Cimzia by showing them your Patient Reminder Card.

Children and adolescents
Cimzia is not recommended for use in children and adolescents under the age of 18 years.

Other medicines and Cimzia
You should **NOT** take Cimzia if you are using the following medicines used to treat rheumatoid arthritis:
- anakinra
- abatacept

If you have questions, please ask your doctor.

Cimzia can be taken together with:
- methotrexate,
- corticosteroids, or
- pain medicines including nonsteroidal anti-inflammatory medicines (also called NSAIDs).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There is limited experience with Cimzia in pregnant women.
Cimzia should only be used during pregnancy if clearly needed. If you are a woman of childbearing potential discuss with your doctor regarding use of adequate contraception while using Cimzia. For women planning pregnancy, contraception may be considered for 5 months after the last Cimzia dose.

If you received Cimzia during your pregnancy, your baby may have a higher risk for getting an infection. It is important that you tell your baby's doctors and other health care professionals about your Cimzia use before the baby receives any vaccine (for more information see section on vaccinations).

Cimzia can be used during breastfeeding.

Driving and using machines
Cimzia may have a minor influence on your ability to drive and use machines. Dizziness (including room spinning sensation, blurred vision and tiredness) may occur after you take Cimzia.

Cimzia contains sodium acetate and sodium chloride
This medicinal product contains less than 1 mmol sodium (23 mg) per 400 mg, i.e. essentially 'sodium-free'.

3. How to use Cimzia

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Rheumatoid arthritis
- The starting dose for adults with rheumatoid arthritis is 400 mg given at weeks 0, 2 and 4.
- This is followed by a maintenance dose of 200 mg every 2 weeks. If you respond to the medicine, your doctor may prescribe an alternative maintenance dosing of 400 mg every 4 weeks.
- Methotrexate is continued while using Cimzia. If your doctor determines that methotrexate is inappropriate, Cimzia can be given alone.

Axial spondyloarthritis
- The starting dose for adults with axial spondyloarthritis is 400 mg given at weeks 0, 2 and 4.
- This is followed by a maintenance dose of 200 mg every 2 weeks (from week 6) or 400 mg every 4 weeks (from week 8) as instructed by your physician. If you have received Cimzia for at least 1 year and respond to the medicine, your physician may prescribe a reduced maintenance dose of 200 mg every 4 weeks.

Psoriatic arthritis
- The starting dose for adults with psoriatic arthritis is 400 mg given at weeks 0, 2 and 4.
- This is followed by a maintenance dose of 200 mg every 2 weeks. If you respond to the medicine, your doctor may prescribe an alternative maintenance dosing of 400 mg every 4 weeks.
- Methotrexate is continued while using Cimzia. If your doctor determines that methotrexate is inappropriate, Cimzia can be given alone.

Plaque psoriasis
- The starting dose for adults with plaque psoriasis is 400 mg every 2 weeks given at weeks 0, 2 and 4.
- This is followed by a maintenance dose of 200 mg every 2 weeks, or 400 mg every 2 weeks as instructed by your physician.

How Cimzia is given
Cimzia will usually be given to you by a specialist doctor or healthcare professional. You will be given Cimzia as either one (200 mg dose) or two injections (400 mg dose) under the skin (subcutaneous use, abbreviation: SC). It is usually injected into the thigh or tummy. However, do not inject in an area where the skin is reddened, bruised, or hard.

Instructions for self-injecting Cimzia
Cimzia solution for injection in a dose-dispenser cartridge (also referred to as “medication”) is intended for single-use in conjunction with the electromechanical injection device called ava. After suitable training, your doctor may allow you to inject Cimzia yourself. Please read the instructions at the end of this leaflet on how to inject Cimzia and in the user manual provided with the injection device ava. Please follow these carefully.

If your doctor has allowed you to self-inject, you should follow up with your doctor before you continue to self-inject:
- after 12 weeks if you have rheumatoid arthritis, axial spondyloarthritis or psoriatic arthritis, or
- after 16 weeks if you have plaque psoriasis.

This is so that the doctor can determine if Cimzia is working for you or if another treatment needs to be considered.

If you use more Cimzia than you should
If your doctor has allowed you to self-inject and you accidentally inject Cimzia more frequently than prescribed, you should tell your doctor. Always take the Patient Reminder Card and the outer carton from the Cimzia package with you, even if it is empty.

If you forget to use Cimzia
If your doctor has allowed you to self-inject and you forget to give yourself an injection, you should inject yourself as soon as you remember and contact your doctor for information. Then, talk to your doctor and inject the following doses as instructed.

If you stop using Cimzia
Do not stop using Cimzia without talking to your doctor first.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor **IMMEDIATELY** if you notice any of the following side effects:
- severe rash, hives or other signs of allergic reaction (urticaria)
- swollen face, hands, feet (angioedema)
- trouble breathing, swallowing (multiple causes for these symptoms)
- shortness of breath with exertion or upon lying down or swelling of the feet (heart failure)
- symptoms of blood disorders such as persistent fever, bruising, bleeding, paleness (pancytopaenia, anaemia, low platelet count, low white blood cell count)
- serious skin rashes. These can appear as reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms. (Stevens-Johnson syndrome)

Tell your doctor **AS SOON AS POSSIBLE** if you notice any of the following side effects:
- signs of infection such as fever, malaise, wounds, dental problems, burning on urination
- feeling weak or tired
- coughing
- tingling
- numbness
- double vision
- arm or leg weakness
- bump or open sore that doesn't heal

The symptoms described above can be due to some of the side effects listed below, which have been observed with Cimzia:

Common (may affect up to 1 in 10 people):
- bacterial infections in any site (a collection of pus)
- viral infections (including cold sores, shingles, and influenza)
- fever
- high blood pressure
- rash or itching
- headaches (including migraines)
- sensory abnormalities such as numbness, tingling, burning sensation
- feeling weak and generally unwell
- pain
- blood disorders
- liver problems
- injection site reactions
- nausea

Uncommon (may affect up to 1 in 100 people):
- allergic conditions including allergic rhinitis and allergic reactions to the medicine (including anaphylactic shock)
- antibody directed against normal tissue
- blood and lymphatic system cancers like lymphoma and leukaemia
- solid organ cancers
- skin cancers, pre-cancerous skin lesions
- benign (non-cancerous) tumours and cysts (including those of the skin)
- heart problems including weakened heart muscle, heart failure, heart attack, chest discomfort or chest pressure, abnormal heart rhythm including irregular heart beats
- oedema (swelling in the face or legs)

- lupus (immune/connective tissue disease) symptoms (joint pain, skin rashes, photosensitivity and fever)
- inflammation of the blood vessels
- sepsis (serious infection which can result in organ failure, shock or death)
- tuberculosis infection
- fungal infections (occur when the ability to fight off infection is lessened)
- respiratory disorders and inflammation (including asthma, shortness of breath, cough, blocked sinuses, pleurisy, or difficulty breathing)
- stomach problems including abdominal fluid collection, ulcers (including oral ulcers), perforation, distension, inflammation heartburn, upset, dry mouth
- bile problems
- muscle problems including increased muscle enzymes
- changes in blood levels of different salts
- changes in cholesterol and fat levels in the blood
- blood clots in the veins or lungs
- bleeding or bruising
- changed numbers of blood cells, including low red cell count (anaemia), low platelet counts, increased platelet counts
- swollen lymph nodes
- flu-like symptoms, chills, altered temperature perception, night sweats, flushing
- anxiety and mood disorders such as depression, appetite disorders, weight change
- ringing in the ears
- vertigo (dizziness)
- feeling faint, including loss of consciousness
- nerve disorders in the extremities including symptoms of numbness, tingling, burning sensation, dizziness, tremor
- skin disorders such as new onset or worsening of psoriasis, inflammation of the skin (such as eczema), sweat gland disorders, ulcers, photosensitivity, acne, hair loss, discoloration, nail separation, dry skin and injuries
- impaired healing
- kidney and urinary problems including impairment of kidney function, blood in the urine and urinary disturbances
- menstrual cycle (monthly period) disorders including lack of bleeding, or heavy or irregular bleeding
- breast disorders
- eye and eyelid inflammation, vision disturbances, problems with tears
- some blood parameters increased (blood alkaline phosphatase increased)
- prolonged coagulation (clotting) test times

Rare (may affect up to 1 in 1,000 people):
- gastrointestinal cancer, melanoma
- lung inflammation (interstitial lung disease, pneumonitis)
- stroke, blockage in blood vessels (arteriosclerosis), poor blood circulation which makes the toes and fingers numb and pale (Raynaud’s phenomenon), mottled purplish skin discoloration, small veins near the surface of the skin may become visible
- pericardial inflammation
- cardiac arrhythmia
- enlarged spleen
- increase of red cell mass
- white blood cell morphology abnormal
- formation of stones in the gall bladder
- kidney problems (including nephritis)
- immune disorders such as sarcoidosis (rash, joint pain, fever), serum sickness, inflammation of the fat tissue, angioneurotic oedema (swelling of the lips, face, throat)
- thyroid disorders (goitre, tiredness, weight loss)

- increased iron levels in the body
- increased blood levels of uric acid
- suicide attempt, mental impairment, delirium
- inflammation of the nerves for hearing, seeing, or of the face, impaired coordination or balance
- increased gastrointestinal motility
- fistula (tract from one organ to another) (any site)
- oral disorders including pain on swallowing
- skin sloughing, blistering, hair texture disorder
- sexual dysfunction
- seizure
- worsening of a condition called dermatomyositis (seen as a skin rash accompanying muscle weakness)
- Stevens-Johnson syndrome (a serious skin condition which early symptoms include malaise, fever, headache and rash)
- inflammatory skin rash (erythema multiforme)
- lichenoid reactions (itchy reddish-purple skin rash and/or threadlike white-grey lines on mucous membranes)

Not known (frequency cannot be estimated from the available data):
- multiple sclerosis*
- Guillain Barré syndrome*
- Merkel cell carcinoma (a type of skin cancer)*

*These events have been related to this class of medicines but the incidence with Cimzia is not known.

Other side effects
When Cimzia has been used to treat other diseases the following uncommon side effects have occurred:
- gastrointestinal stenosis (narrowing of part of the digestive system).
- gastrointestinal obstructions (blockages of the digestive system).
- general physical health deterioration.
- spontaneous abortion.
- azoospermia (lack of sperm production).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:
The Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cimzia

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pack and dose-dispenser cartridge after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C).
Do not freeze.
Keep the dose-dispenser cartridge in the outer carton in order to protect from light.

The dose-dispenser cartridges may be stored at room temperature (up to 25°C) for a single period of maximum 10 days with protection from light. At the end of this period the dose-dispenser cartridges **must be used or discarded**.

Do not use this medicine if the solution is discoloured, cloudy or if you can see particles in it.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Cimzia contains
- The active substance is certolizumab pegol. Each dose-dispenser cartridge contains 200 mg of certolizumab pegol in one ml.
- The other ingredients are: sodium acetate, sodium chloride and water for injection (see “Cimzia contains sodium acetate and sodium chloride” in section 2).

What Cimzia looks like and contents of the pack
Cimzia is provided as a solution for injection in a ready to use dose-dispenser cartridge. The dose-dispenser cartridge is to be used with the electromechanical injection device ava. The device is provided separately. The solution is clear to opalescent, colourless to yellow.

One Cimzia pack contains:
- two dose-dispenser cartridges of solution, and
- two alcohol wipes (for cleansing the areas chosen for injection).

Packs of 2 dose-dispenser cartridges and 2 alcohol wipes, a multipack containing 6 (3 packs of 2) dose-dispenser cartridges and 6 (3 packs of 2) alcohol wipes, and a multipack containing 10 (5 packs of 2) dose-dispenser cartridges and 10 (5 packs of 2) alcohol wipes are available.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
UCB Pharma S.A.
Allée de la Recherche 60
B-1070 Bruxelles
Belgium

Manufacturer
UCB Pharma S.A.
Chemin du Foriest
B-1420 Braine l'Alleud
Belgium

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/Belgien
UCB Pharma S.A./NV
Tel/Tél: + 32 / (0)2 559 92 00

България
Ю СИ БИ България ЕООД
Тел.: + 359 (0) 2 962 30 49

Lietuva
UCB Pharma Oy Finland
Tel: + 358 9 25144221

Luxembourg/Luxemburg
UCB Pharma S.A./NV
Tél/Tel: + 32 / (0)2 559 92 00

Česká republika
UCB s.r.o.
Tel: + 420 221 773 411

Danmark
UCB Nordic A/S
Tlf: + 45 / 32 46 24 00

Deutschland
UCB Pharma GmbH
Tel: + 49 /(0) 2173 48 4848

Eesti
UCB Pharma Oy Finland
Tel: + 358 9 25144221

Ελλάδα
UCB A.E.
Τηλ: + 30 / 2109974000

España
UCB Pharma S.A.
Tel: + 34 / 91 570 34 44

France
UCB Pharma S.A.
Tél: + 33 / (0)1 47 29 44 35

Hrvatska
Medis Adria d.o.o.
Tel: +385 (0) 1 230 34 46

Ireland
UCB (Pharma) Ireland Ltd.
Tel: + 353 / (0)1-46 37 395

Ísland
Vistor hf.
Tel: + 354 535 7000

Italia
UCB Pharma S.p.A.
Tel: + 39 / 02 300 791

Κύπρος
Lifepharma (Z.A.M.) Ltd
Τηλ: + 357 22 34 74 40

Latvija
UCB Pharma Oy Finland
Tel: + 358 9 25144221

Magyarország
UCB Magyarország Kft.
Tel.: + 36-(1) 391 0060

Malta
Pharmasud Ltd.
Tel: + 356 / 21 37 64 36

Nederland
UCB Pharma B.V.
Tel.: + 31 / (0)76-573 11 40

Norge
UCB Nordic A/S
Tlf: + 45 / 32 46 24 00

Österreich
UCB Pharma GmbH
Tel: + 43-(0)1 291 80 00

Polska
UCB Pharma Sp. z o.o.
Tel.: + 48 22 696 99 20

Portugal
UCB Pharma (Produtos Farmacêuticos), Lda
Tel: + 351 / 21 302 5300

România
UCB Pharma Romania S.R.L.
Tel: + 40 21 300 29 04

Slovenija
Medis, d.o.o.
Tel: + 386 1 589 69 00

Slovenská republika
UCB s.r.o., organizačná zložka
Tel: + 421 (0) 2 5920 2020

Suomi/Finland
UCB Pharma Oy Finland
Puh/Tel: + 358 9 25144221

Sverige
UCB Nordic A/S
Tel: + 46 / (0) 40 29 49 00

United Kingdom
UCB Pharma Ltd.
Tel : + 44 / (0)1753 534 655

This leaflet was last revised in 07/2020

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu

INSTRUCTIONS FOR USE FOR THE CIMZIA INJECTION BY MEANS OF A DOSE-DISPENSER CARTRIDGE

Important information

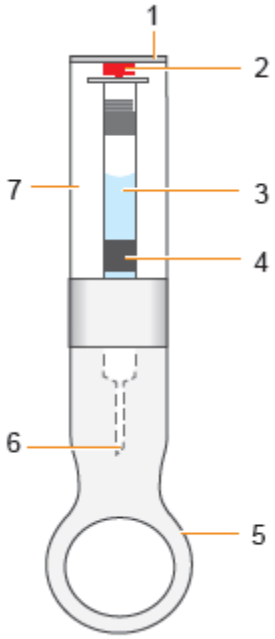
Read the instructions below carefully – this explains how to inject Cimzia by means of a dose-dispenser cartridge. The dose-dispenser cartridge is also referred to as “medication”.

- The medication is to be used with the electromechanical injection device called “ava” which is provided separately.
- **You must also carefully read the full instructions in the ava User Manual.**

You can inject yourself or the injection can be given by someone else (caregiver).
If your doctor says you can inject yourself, you need to be fully trained first.

- You will be instructed by your doctor or healthcare giver how to inject the medicine.
- If something is not clear – please ask your doctor or pharmacist.

Medication: dose-dispenser cartridge



1. End cap
2. Medication level indicator
3. Syringe
4. Medication information chip
5. Needle cap
6. Needle (inside cap)
7. Medication body

Injection device: ava

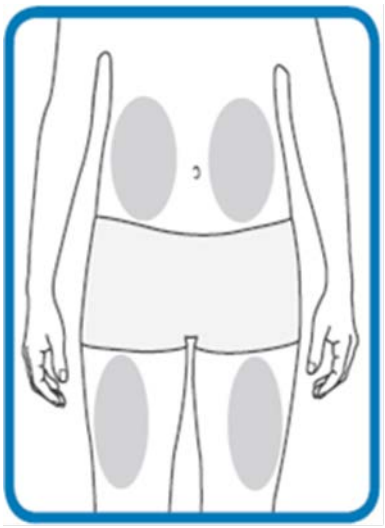
1. On/Off Button
2. Start/Pause button
3. Cartridge/Injection port
4. Skin sensor (the skin sensor detects when the injection port is fully in contact with your skin).
5. Scroll wheel (to adjust the speed of injection)
6. Information screen
7. Micro-USB Port

1. Setting up

- Remove the Cimzia carton from the refrigerator.
  – If the seal(s) is missing or broken – do not use and contact your pharmacist.
- Remove the following items from the Cimzia pack and set them up on a clean flat surface:
  – One or two medication cartridge(s), depending on your prescribed dose
  – One or two alcohol wipe(s)
- Look at the expiry date on the medication and pack. Do not use Cimzia after the expiry date which is stated on the pack and medication after EXP. The expiry date refers to the last day of the month shown.
- Allow the medication to reach room temperature. This will take from 30 to 45 minutes. This will help reduce discomfort when injecting.
  – Do not heat the medication - let it warm up on its own.
  – Use a clean dry cloth to wipe off any condensation on the outside of the cartridge.
- Do not remove the needle cap until ava instructs you to do so.
- Wash your hands thoroughly.

2. Choosing and preparing an injection site

- Choose a site on your thighs or tummy.



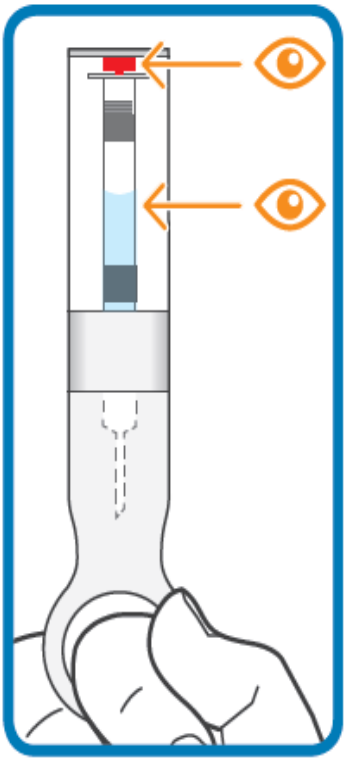
- Each new injection should be given on a site separate from the last injection site.
  - Do not inject in an area where the skin is reddened, bruised, or hard.
  - Wipe the injection site with an alcohol wipe, using a circular motion moving from the inside out.
  - Do not touch the area again before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

3. Injection

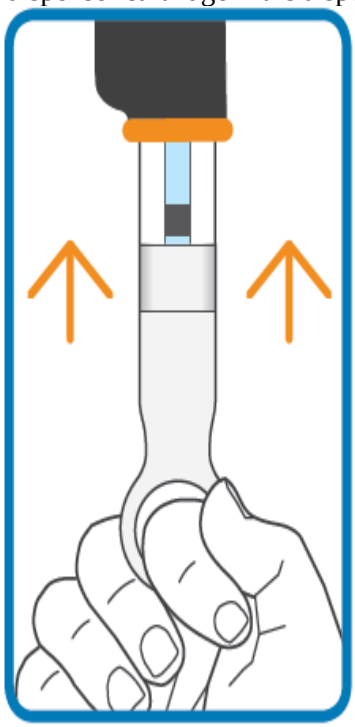
- If you feel unsure about the injection process, contact your doctor or pharmacist.
- Do not shake the medication.
- Do not use the medication if it has been dropped after taking it out of the pack.
- Turn on ava:
  - Press the (On/Off button) for 1 second, or until the screen lights up and you hear sound
  - "Hello" is displayed for 2 seconds - this means ava is switched on.
- ava then shows:
  - Your current dose and how often you need to inject it,
  - This is then followed by the message, "Inspect and then insert medication".

Check the medicine through the medication body.
  - Do not use if the solution is discoloured, cloudy or there are particles in it.
  - You may see air bubbles - this is normal. Injecting a solution subcutaneously which contains air bubbles is harmless.

Check that the red "medication level indicator" is at the top of the cartridge.
  - The medication contains 1ml of Cimzia and is not completely full - this is normal.
  - Do not remove the needle cap from the medication yet.

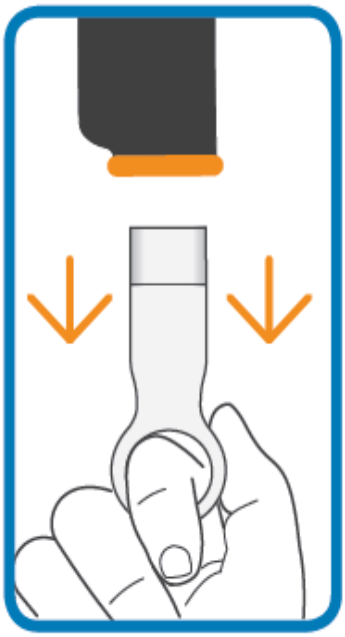


- Firmly push the flat end cap into the medication/injection port at the bottom of ava – push until you hear a click.
  – Do not twist the dose-dispenser cartridge - it is a special shape so that it fits correctly.

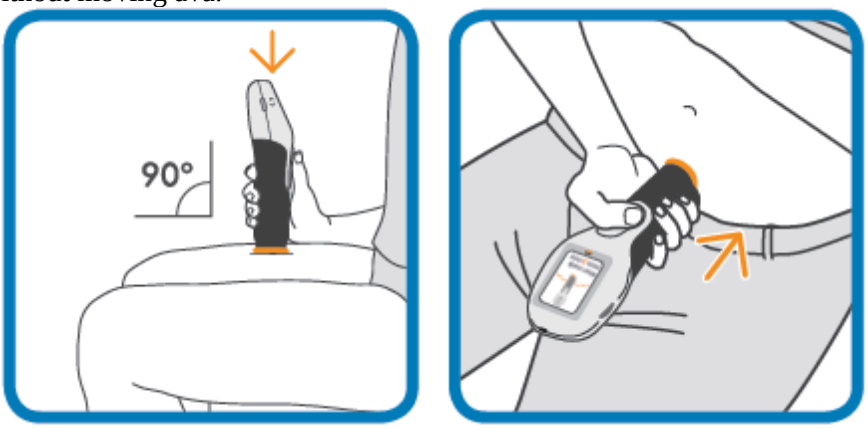


- Let go of the needle cap – this allows ava to check if the medication is usable. Do not remove the needle cap.
  – "Medication accepted" is shown if it is correct.
  – After a short pause, ava will automatically pull the cartridge in further.
- The current injection speed (medication flow rate) is shown.
  – You can change this speed using the "scroll wheel" on the side of your ava.
  – You can choose "slowest", "slow", "fast" or "fastest" - this controls how fast the medicine will be injected and should be selected (and adjusted) as per your personal comfort preference. Your doctor can provide advice.
- "Remove and save needle cap" is shown.

  - Only remove the needle cap when you are ready to inject.
- When ready, remove the needle cap by pulling it firmly downwards.
  - Once the needle cap has been removed, you must give the injection within 5 minutes. There is no need to rush your injection - 5 minutes gives you enough time. The time left is shown on screen.
  - **Keep the needle cap -** you will need it to remove the used medication from ava later.



- Find a comfortable position and sit down for your injection.
  - Try to relax as this will make the injection more comfortable.
- Place the orange skin sensor against the injection site where you are going to inject.
  - Position ava at a right angle on your skin with the screen facing you. This will make sure you are giving the injection correctly.
  - Position ava as shown so that you can comfortably reach the (Start/Pause button) without moving ava.



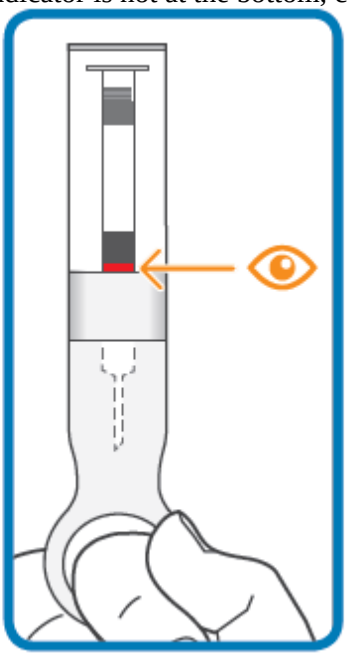
- Once ava is placed firmly against your skin “When ready press > once” is shown.
- Press the (Start/Pause button).
  - As the injection is being given, keep holding ava firmly against your skin.
  - Avoid removing ava from the skin during the injection to ensure that you receive the full dose.
  - If ava is accidentally removed from your skin during the injection, the injection will automatically stop and the needle will go back into ava. To complete your injection:
    - Repeat Step 2 (Choosing and preparing an injection site), using a different injection site
    - Press ava firmly against the skin to begin the injection again, then

- Press the  (Start/Pause button).

- If you feel unsure about the injection process, please contact your doctor or pharmacist. Do not try to repeat the injection process without speaking to your doctor or your pharmacist.
- When the injection is complete, a message is shown on ava's screen saying "Injection complete. Please remove from skin" - you can then remove ava from you skin.

- Use a piece of gauze, 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.
- The messages “Needle uncapped! Handle with care!” and “Please replace needle cap” are shown until the needle cap is put back on.
- Replace the needle cap.
- Let go of the needle cap so that ava can push out the used medication.
- When “Remove and discard used medication” is shown, pull out the medication using the needle cap.

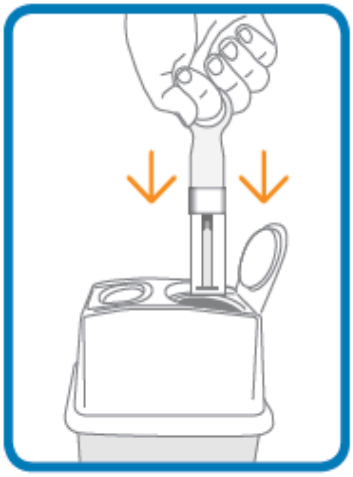
Check the red medication level indicator is at the bottom of the cartridge - this shows you have had all of your injection. If the indicator is not at the bottom, contact your pharmacist.



4. After Use

- Do not re-use the cartridge
- After injection, immediately throw away the used cartridge(s) in a special container as instructed by your doctor, nurse or pharmacist.
- Keep the container out of the sight and reach of children.
- If you need to have a second injection as prescribed by your doctor:
  - The message “You have 1 injection left” will be shown on screen.

– Repeat the injection process starting at Step 2.



- Store ava in the storage case after use.