

Package leaflet: Information for the user

Cimzia 200 mg solution for injection in pre-filled syringe 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

1. What Cimzia is and what it is used for
2. What you need to know before you use Cimzia
3. How to use Cimzia
4. Possible side effects
5. How to store Cimzia
6. Contents of the pack and other information

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 (TNF α). Thereby this TNF α is blocked by Cimzia and this decreases inflammation diseases such as in rheumatoid arthritis, axial spondyloarthritis, psoriatic arthritis and psoriasis. Medicines that bind to TNF α 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.

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

Tell your doctor before treatment with 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

After suitable training, your doctor may also allow you to inject Cimzia yourself. Please read the instructions at the end of this leaflet on how to inject Cimzia.

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 the next dose of Cimzia as soon as you remember. 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 (pancytopenia, 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)*
- Kaposi's sarcoma (a rare cancer related to infection with human herpes virus 8. Kaposi's sarcoma most commonly appears as purple lesions on the skin)

*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:

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 syringe 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 pre-filled syringe in the outer carton in order to protect from light.

The pre-filled syringes 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 pre-filled syringes **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 pre-filled syringe 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 pre-filled syringe. The solution is clear to opalescent, colourless to yellow.

One Cimzia pack contains:

- two pre-filled syringes of solution, and
- two alcohol wipes (for cleansing the areas chosen for injection).

Packs of 2 pre-filled syringes and 2 alcohol wipes, a multipack containing 6 (3 packs of 2) pre-filled syringes and 6 (3 packs of 2) alcohol wipes, and a multipack containing 10 (5 packs of 2) pre-filled syringes and 10 (5 packs of 2) alcohol wipes are available.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

UCB Pharma Limited
208 Bath Road
Slough
Berkshire
SL1 3WE
United Kingdom

Manufacturer

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

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INSTRUCTIONS FOR USE FOR CIMZIA INJECTION BY MEANS OF A PRE-FILLED SYRINGE

After proper training, the injection can be self-administered or given by another person, for example a family member or friend. The following instructions explain how to inject Cimzia. Please read the instructions carefully and follow them step by step. You will be instructed by your doctor or healthcare giver on the technique of self-injection. Do not attempt to self-inject until you are sure that you understand how to prepare and give the injection.

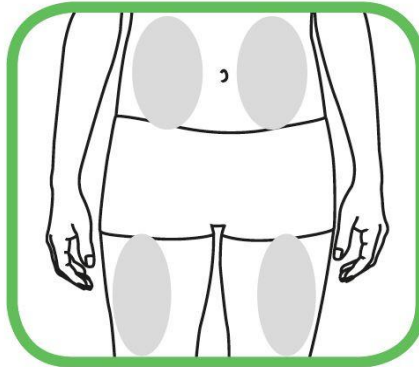
This injection should not be mixed in the same syringe with any other medicine.

1. Setting up

- Remove the Cimzia pack 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 pre-filled syringe(s), depending on your prescribed dose
 - One or two alcohol wipe(s)
- Look at the expiry date on the syringe and pack. Do not use Cimzia after the expiry date which is stated on the pack and syringe after EXP. The expiry date refers to the last day of the month shown.
- Allow the pre-filled syringe to reach room temperature. This will take 30 minutes. This will help reduce discomfort when injecting.
 - Do not heat the pre-filled syringe – let it warm on its own.
- Do not remove the cap until you are ready to inject.
- Wash your hands thoroughly.

2. Choosing and preparing an injection site

- Choose a site on your thigh or tummy.



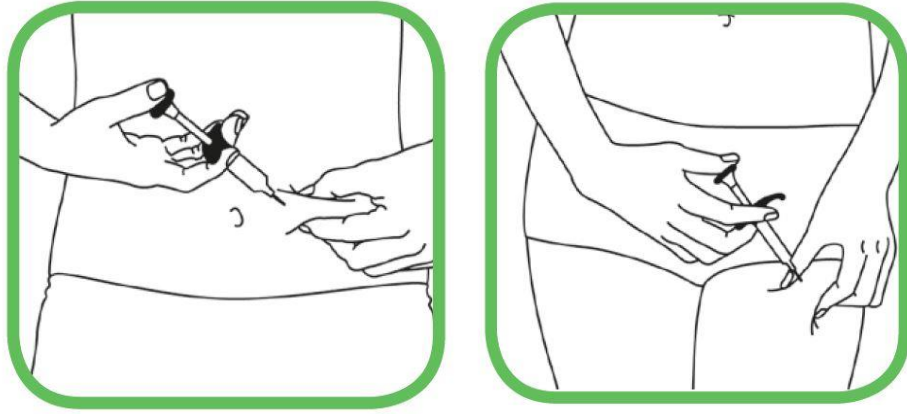
- Each new injection should be given on a separate site from the last injection site.
 - Do not inject in an area where the skin is reddened, bruised, or hard.
 - Wipe the injection site with the enclosed alcohol wipe, using a circular motion moving from the inside out.
 - Do not touch the area again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

3. Injection

- Do not shake the syringe.



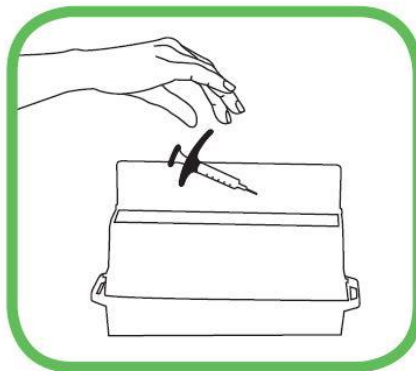
- Check the medicine in the body of the syringe.
 - Do not use if the solution is discoloured, cloudy or if you can see particles in it.
 - You may see air bubbles - this is normal. Injecting a solution subcutaneously which contains air bubbles is harmless.
- Remove the cap from the needle in a straight direction, being careful not to touch the needle or let the needle touch any surface. Do not bend the needle.
- Inject within 5 minutes of removing the needle cap.
- Gently grasp the cleaned area of 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.
- 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.
- Release the skin with the first hand.
- 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.

4. After Use

- Do not re-use the syringe or re-cap the needle.
- After injection, immediately throw away the used syringe(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 repeat the injection process starting at Step 2.