PATIENT INFORMATION LEAFLET (PIL)

SCHEDULING STATUS
Schedule 4

SIMPONI®

Solution for Injection for subcutaneous administration

Golimumab

Contains sugar (sorbitol).

Each pre-filled syringe and/or pre-filled pen contains 20,5 mg sorbitol (E420) per 50 mg dose.

Read all of this leaflet carefully before you start using SIMPONI

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- SIMPONI has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What SIMPONI is and what it is used for

2. What you need to know before you use SIMPONI

3. How to use SIMPONI

4. Possible side effects

5. How to store SIMPONI

6. Contents of the pack and other information

1. What SIMPONI is and what it is used for

SIMPONI contains the active substance called golimumab.

SIMPONI belongs to a group of medicines called 'TNF blockers'. SIMPONI works by blocking the action of a protein called 'tumour necrosis factor alpha' (TNF-α). This protein is involved in inflammatory processes of the body, and blocking it can reduce the inflammation in your body.

SIMPONI is used in **adults** for the treatment of:

- Rheumatoid arthritis (inflammatory disease of the joints),
- Psoriatic arthritis (inflammatory disease of the joints, usually accompanied by psoriasis),
- Ankylosing spondylitis (inflammatory disease of the spine),
- Non-radiographical axial spondyloarthritis (inflammatory disease of the spine with no changes in the x-ray) and
- Ulcerative colitis (inflammatory disease of the bowel).

In children 2 years of age and older, SIMPONI is used for the treatment of polyarticular juvenile idiopathic arthritis (inflammatory disease that causes joint pain and swelling in children). If your child has polyarticular juvenile idiopathic arthritis, your child will first be given other medicines. If your child does not respond well enough to these medicines, your child will be given SIMPONI in combination with methotrexate to treat the disease)

2. What you need to know before you use SIMPONI

Do not use SIMPONI

- If you are hypersensitive (allergic) to golimumab or any of the other ingredients of SIMPONI listed in section 6.
- If you have tuberculosis (TB) or any other severe infection.
- If you have moderate to severe heart failure.
- If you have received or are going to receive live vaccine(s).
- If you have or have had lymphoma (a type of blood cancer).
- If you have a history of neurological disease.
- If you are pregnant or breastfeeding.

If you are not sure if any of the above applies to you, talk to your doctor, pharmacist or nurse before using SIMPONI.

Warnings and precautions

Tell your doctor or health care provider before being given the injection if you:

- have any kind of infection even if it is very minor,
- have an infection that won't go away or a history of infection that keeps coming

back,

- have had TB (tuberculosis), or if you have recently been in contact with anyone who might have TB. Your doctor will evaluate you for TB and perform skin or a blood test. If you doctor feels that you are at risk for TB, he or she may start treating you for TB before you begin SIMPONI therapy,
- have lived in or travelled to an area where infections called histoplasmosis, coccidioidomycosis**,** Listeria and Legionella or blastomycosis are common. These infections are caused by fungus that can affect the lungs or other parts of your body. Ask your doctor if you do not know if these infections are common in the area in which you have lived or travelled.

- have or have had hepatitis B infection,
- have heart failure, or if you previously had or currently have any heart condition. If you develop new or worsening symptoms of heart failure, such as shortness of breath or swelling of your feet, you must notify your doctor,
- have or have had a condition that affects your nervous system, like multiple sclerosis or Guillain-Barré syndrome. You should tell your doctor if you experience weakness in the arms or legs, numbness, tingling or visual disturbances,
- have or have had any type of cancer,
- have recently received or are scheduled to receive a vaccine,
- have recently received or are scheduled to receive treatment with a therapeutic infectious medicine (such as BCG instillation used for the treatment of cancer),
- have a latex allergy,
- received SIMPONI while you were pregnant as your baby may be at higher risk for getting an infection. It is important to tell your baby's doctor and other healthcare professionals about your SIMPONI use before the baby receives any vaccine as certain vaccines may put your baby at higher risk for infections.

Children

SIMPONI is not recommended for children less than 2 years of age with polyarticular juvenile idiopathic arthritis because it has not been studied in this group.

Other medicines and SIMPONI

- Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).
- Tell your doctor or pharmacist if you are taking anakinra or abatacept because it should not be taken together.
- Also tell your doctor or pharmacist if you are taking any other medicines that affect your immune system.
- You should not receive certain (live) vaccines while using SIMPONI.

SIMPONI with food and drink

SIMPONI can be administered with or without food or drink.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

SIMPONI should not be used by pregnant women. You are advised to avoid becoming pregnant while using SIMPONI and should use appropriate contraceptives.

SIMPONI should not be used by mothers who are breastfeeding their infants.

Driving and using machines

SIMPONI may cause dizziness. You should not drive or operate machines until you are sure that your ability to perform such activities is not affected by SIMPONI.

SIMPONI contains sorbitol and latex

Sorbitol intolerance

SIMPONI contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using SIMPONI.

Latex sensitivity

A part of the pre-filled pen, the needle cover, contains latex. Because latex may cause severe allergic reactions, talk to your doctor before using SIMPONI if you or your caregiver are allergic to latex.

3. How to use SIMPONI

Do not share medicines prescribed for you with any other person.

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

Your doctor will tell you how long your treatment with SIMPONI will last. Do not stop treatment early because your symptoms may return. If you have the impression that the effect of SIMPONI is too strong or too weak, tell your doctor or pharmacist.

SIMPONI is intended for use under the guidance and supervision of your doctor. It is injected under the skin (subcutaneous use) with a pre-filled syringe or pre-filled pen. Your doctor will tell you how often to administer SIMPONI. Do not take SIMPONI more often than prescribed. If your doctor determines that it is appropriate, you may be able to administer SIMPONI to yourself, after proper training of injection technique (see the Instructions for injecting SIMPONI under the skin yourself").

Dosing for adults 18 years and older:

The recommended dose is 50 mg subcutaneously given once a month, on the same date each month, for rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and non-radiographic Axial spondyloarthritis.

For ulcerative colitis, SIMPONI is injected under the skin (subcutaneous use) with a pre-filled syringe or a pre-filled pen, as an initial dose of 200 mg, followed by 100 mg at week 2, then 50 mg every 4 weeks, thereafter. The maintenance dose of 100 mg every 4 weeks can be

considered at the discretion of the treating medical practitioner. During maintenance treatment, corticosteroids may be tapered in accordance with clinical practice guidelines.

Dosing for children weighing at least 40 kg for polyarticular juvenile idiopathic arthritis

SIMPONI 50 mg is given by injection under the skin with a pre-filled syringe or autoinjector once a month, on the same date each month. Talk to the child's doctor before your child takes their fourth dose. Your child's doctor will determine if they should continue treatment with SIMPONI.

Dosing for children weighing less than 40 kg for polyarticular juvenile idiopathic arthritis

For patients weighing less than 40 kg, a 45 mg/0,45 mL pre-filled pen is available. Your doctor will tell you the correct dose to use.

If you administer more SIMPONI than you should

If you administer more SIMPONI than you were told to take, call your doctor. Always take the outer carton and this leaflet with you, even if it is empty.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to administer SIMPONI

If you forget to administer SIMPONI on your scheduled date, inject a dose as soon as you remember. Do not administer a double dose to make up for forgotten individual doses. Then administer your next dose at your regularly scheduled date. This will put you back on your

schedule. In case you are not sure when to inject SIMPONI, contact your doctor or pharmacist.

Effects when treatment with SIMPONI is stopped

It is not dangerous to stop using SIMPONI. However, the symptoms for which SIMPONI was prescribed may return.

If you have any further questions on the use of SIMPONI, ask your doctor or pharmacist.

4. Possible side effects

SIMPONI can have side effects.

Not all side effects reported for SIMPONI are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SIMPONI, please consult your health care provider for advice.

Tell your doctor straight away if you notice any of the following serious side effects of SIMPONI which include:

- **Allergic reactions which may be serious, or rarely, life-threatening:**
  Symptoms of an allergic reaction may include swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, skin rash, hives, swelling of the hands, feet or ankles. Some of these reactions occurred after the first administration of SIMPONI.
- **Serious infections (including TB, bacterial infections including serious blood infections and pneumonia, severe fungal infections and other opportunistic infections).** Symptoms of an infection can include fever, tiredness, (persistent) cough,

shortness of breath, flu-like symptoms, weight loss, night sweats, diarrhoea, wounds, dental problems and a burning feeling when urinating.

- **Reactivation of hepatitis B virus if you are a carrier or have had hepatitis B before.** Symptoms can include yellowing of the skin and eyes, dark brown-coloured urine, right-sided abdominal pain, fever, feeling sick, being sick, and feeling very tired.
- **Nervous system disease such as multiple sclerosis.** Symptoms of nervous system disease can include changes in your vision, weakness in your arms or legs, numbness or tingling in any part of your body.
- **Cancer of the lymph nodes (lymphoma).** Symptoms of lymphoma can include swelling of the lymph nodes, weight loss, or fever.
- **Heart failure.** Symptoms of heart failure can include shortness of breath or swelling of your feet.
- **Signs of immune system disorders called:**
  - **Lupus.** Symptoms can include joint pain or a rash on cheeks or arms that is sensitive to the sun.
  - **Sarcoidosis.** Symptoms can include a persistent cough, being short of breath, chest pain, fever, swelling of your lymph nodes, weight loss, skin rashes, and blurred vision.
- **Swelling of small blood vessels (vasculitis).** Symptoms can include fever, headache, weight loss, night sweats, rash, and nerve problems such as numbness and tingling.
- **Skin cancer.** Symptoms of skin cancer can include changes in the appearance of your skin or growths on your skin.
- **Blood disease.** Symptoms of blood disease can include a fever that does not go away, bruising or bleeding very easily or looking very pale.

- **Blood cancer (leukaemia)**. Symptoms of leukaemia can include fever, feeling tired, frequent infections, easy bruising, and night sweats.

Tell your doctor straight away if you notice any of the above symptoms.

The following additional side effects have been observed with SIMPONI:

Frequent side effects:

- Upper respiratory tract infections, sore throat or hoarseness, runny nose
- Abnormal liver tests (increased liver enzymes) found during blood tests done by your doctor
- Feeling dizzy
- Headache
- Feeling numb or having a tingling feeling
- Superficial fungal infections (e.g. which include the skin or mucous membranes, nails, or hair, e.g. yeast vaginitis, oral thrush and athletes' foot),
- Abscess
- Bacterial infections (such as cellulitis involves the skin's deeper layers: the dermis and subcutaneous tissue with symptoms such as redness or inflammation, swelling, pain, tenderness and warmth of the affected area)
- Low red blood cell counts
- Low white blood cell counts
- Positive blood lupus test
- Allergic reactions
- Indigestion
- Stomach pain
- Feeling sick (nausea)

- Flu
- Bronchitis
- Sinus infection
- Cold sores
- High blood pressure
- Fever
- Asthma, shortness of breath, wheezing
- Stomach and bowel disorders which include inflammation of the stomach lining and colon which may cause fever
- Pain and ulcers in the mouth
- Injection site reactions (including redness, hardness, pain, bruising, itching, tingling and irritation)
- Hair loss
- Rash and itching of the skin
- Difficulty sleeping
- Depression
- Feeling weak
- Bone fractures
- Chest discomfort.

Less frequent side effects

- Kidney infection
- Cancers, including skin cancer and non-cancerous growths or lumps, including skin moles
- Skin blisters

- Severe infection throughout the body (sepsis), sometimes including low blood pressure (septic shock)
- Psoriasis (including on the palms of your hand and/or the soles of your feet and/or in the form of skin blisters)
- Low platelet count
- Combined low platelet, red, and white blood cell count
- Thyroid disorders
- Increase in blood sugar levels
- Increase in blood cholesterol levels
- Balance disorders
- Vision disturbances
- Inflamed eye (conjunctivitis)
- Eye allergy
- Sensation of heart beating irregularly
- Narrowing of the blood vessels in the heart, which causes signs and symptoms of heart disease, such as chest pain (angina)
- Blood clots that form inside the blood vessels, such as deep vein thrombosis
- Flushing
- Constipation
- Stomach and bowel disorders which include inflammation of the stomach lining and large bowel (colon) which may cause fever
- Chronic inflammatory condition of the lungs
- Acid reflux
- Pain and ulcers in the mouth
- Gall stones
- Liver disorders

- Breast disorders
- Menstrual disorders
- Failure of the bone marrow to produce blood cells
- Severely decreased number of white blood cells
- Infection of the joints or the tissue around them
- Impaired healing
- Inflammation of blood vessels in internal organs
- Leukaemia
- Melanoma (a type of skin cancer)
- Merkel cell carcinoma (a type of skin cancer)
- Lichenoid reactions (itchy reddish-purple skin rash and/or threadlike white-grey lines on mucous membranes)
- Scaly, peeling skin
- Immune disorders that could affect the lungs, skin and lymph nodes (most commonly presenting as sarcoidosis)
- Pain and discolouration in the fingers or toes
- Taste disturbances
- Bladder disorders
- Kidney disorders
- Inflammation of the blood vessels in your skin which results in rash
- A rare blood cancer affecting mostly young people (hepatosplenic T-cell lymphoma)
- Worsening of a condition called dermatomyositis (seen as a skin rash accompanying muscle weakness).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"** found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SIMPONI.

5. How to store SIMPONI

Store all medicine out of reach of children.

Store at 2 to 8 °C (in a refrigerator). Do not freeze. Do not shake. Keep the pre-filled syringe and the pre-filled pen in the outer carton in order to protect from light.

Do not use SIMPONI after the expiry dated stated on the label and carton. The expiry date refers to the last day of that month.
Do not use SIMPONI if the solution is discoloured, cloudy or you can see foreign particles in it.

Do not use if you know, or think that it may have been exposed to extreme temperatures (such as accidently frozen or heated).

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SIMPONI contains

The active substance is golimumab. One 0,50 mL pre-filled pen contains 50 mg of golimumab.

The other ingredients are sorbitol (E420), histidine, histidine hydrochloride monohydrate, polysorbate 80 and water for injections. For more information on sorbitol (E420), see Section 2.

What SIMPONI looks like and contents of the pack

SIMPONI is supplied in Type 1 glass syringes with fixed stainless steel needles as single use pre-filled syringes available in carton packs of 1 or 3 pre-filled syringes.

SIMPONI is supplied in a Type 1 glass syringe with a fixed stainless steel needle. This syringe is contained in a single-use pre-filled pen called “SmartJect” available in carton packs of 1 or 3 pre-filled pens.

The solution is clear to slightly opalescent, colourless to light yellow and may contain a few small translucent or white particles of protein. This appearance is not unusual for solutions that contain protein.

Holder of certificate of registration



JANSSEN PHARMACEUTICA (Pty) Ltd

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Registration number: 43/30.1/0808

Access to the corresponding Professional Information:

Included in the carton, accompanying this patient information leaflet.

Instructions for Use

SIMPONI 50 mg/0,50 mL

Instructions for injecting SIMPONI under the skin yourself

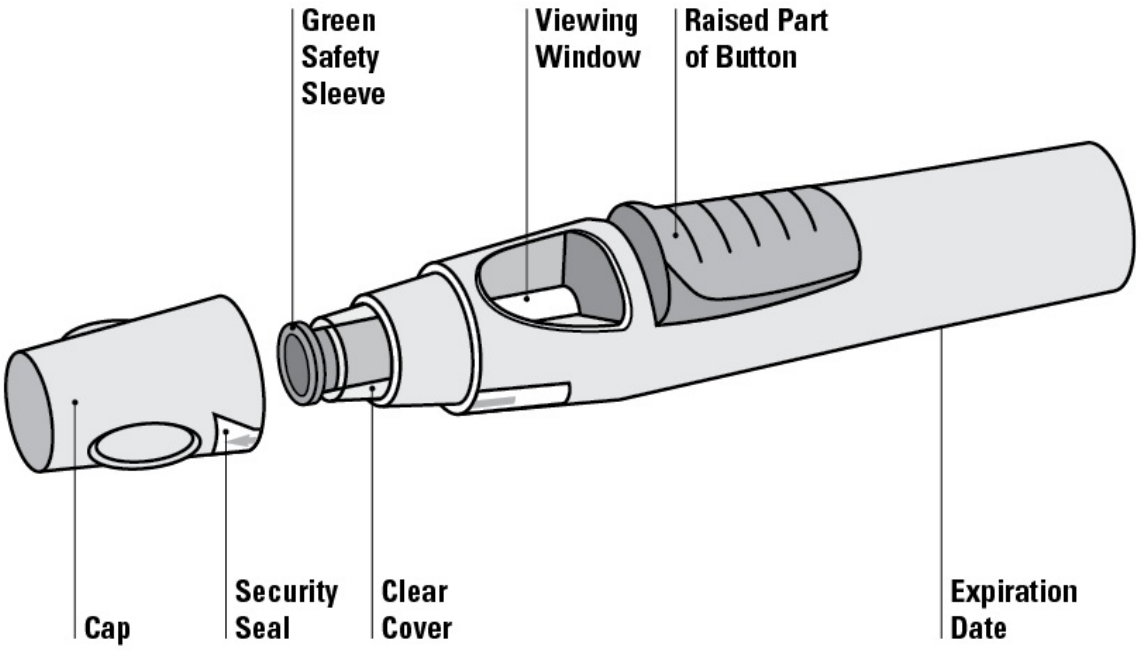
At the start of your therapy, SIMPONI may be injected by medical or nursing staff. However, your doctor may decide that it is right for you or your caregiver to learn to inject SIMPONI under the skin (subcutaneous) yourself. Make sure you (or your caregiver) have been trained how to inject SIMPONI before you do it yourself. Call your doctor if you have any questions about giving yourself an injection.

Instructions for injecting SIMPONI using a single use autoinjector/pre-filled pen

If you would like to self-inject SIMPONI, you must be trained by a healthcare professional to prepare an injection and give it to yourself. If you have not been trained, please contact your healthcare professional to schedule a training session.

STEP 1: PREPARING TO USE THE AUTOINJECTOR

The diagram below shows what the autoinjector looks like:



Do **NOT** shake the autoinjector at any time

Do **NOT** remove the autoinjector cap from the pen until immediately before the injection.

Check Expiry Date

- Check the expiry date (as indicated as “EXP”) on the autoinjector
- You can also check the expiry date printed on the carton
- If the expiry date has passed, do not use the autoinjector and please contact your doctor or pharmacist.

Check Security Seal

- Check the security seal around the cap of the autoinjector. If the security seal is broken, do not use the autoinjector and please contact your doctor or pharmacist.

Wait 30 minutes

- To ensure proper injection, expose the autoinjector to room temperature outside the carton for 30 minutes and out of the reach of children



Do **NOT** warm the autoinjector in any other way (for example, Do **NOT** warm it in a microwave or in hot water)

Do **NOT** remove the autoinjector cap while allowing it to reach room temperature

Assemble additional supplies

- Assemble additional supplies you will need for your injection. These include an alcohol swab, a cotton ball or gauze, and a sharps container

Check the liquid in the Autoinjector

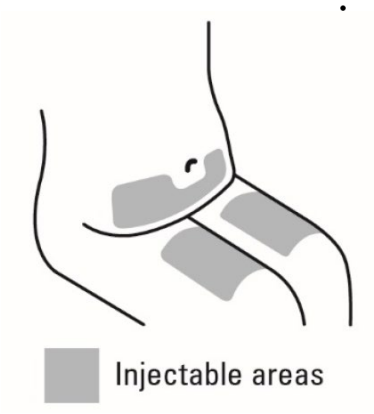
- Look through the viewing window to make sure that the liquid in the autoinjector is clear to slightly opalescent and colourless to slightly yellow
- You may also notice an air bubble – this is normal

Do **NOT** use if the liquid is discoloured, cloudy or contains particles. If this is the case, please contact your doctor or pharmacist.

STEP 2: CHOOSING AND PREPARING THE INJECTION SITE

Choose the Injection Site

- Front of the middle thighs
- You can also use the lower abdomen below the belly button, except for the 5 centimeter area directly underneath the belly button
- Do NOT inject into the arm



- If multiple injections are required for a single administration, the injections should be administered at different sites on the body

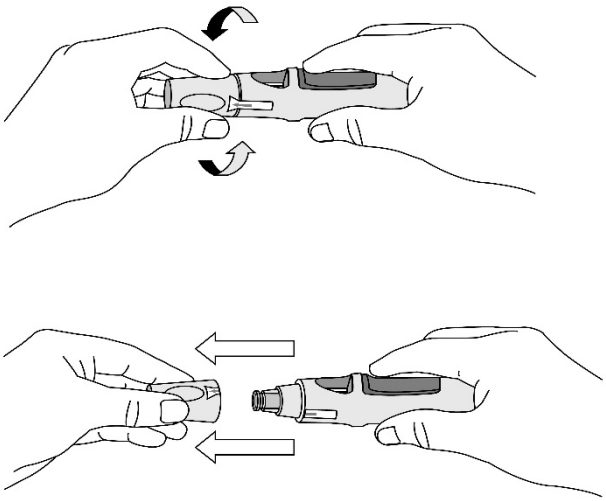
Do **NOT** inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks.

Preparing Injection Site

- Thoroughly wash your hands with soap and warm water
- Wipe the injection site with an alcohol swab

Do **NOT** touch this area again before giving the injection. Allow the skin to dry before injecting.

Do **NOT** fan or blow on the clean area.



STEP 3: INJECTING THE MEDICINE

Remove the Cap

The cap should **NOT** be removed until you are ready to inject SIMPONI.

SIMPONI should be injected within 5 minutes after the cap has been removed.

- When you are ready to inject, twist the cap slightly to break the security seal
- Pull the cap off and immediately place the cap into the trash bin.

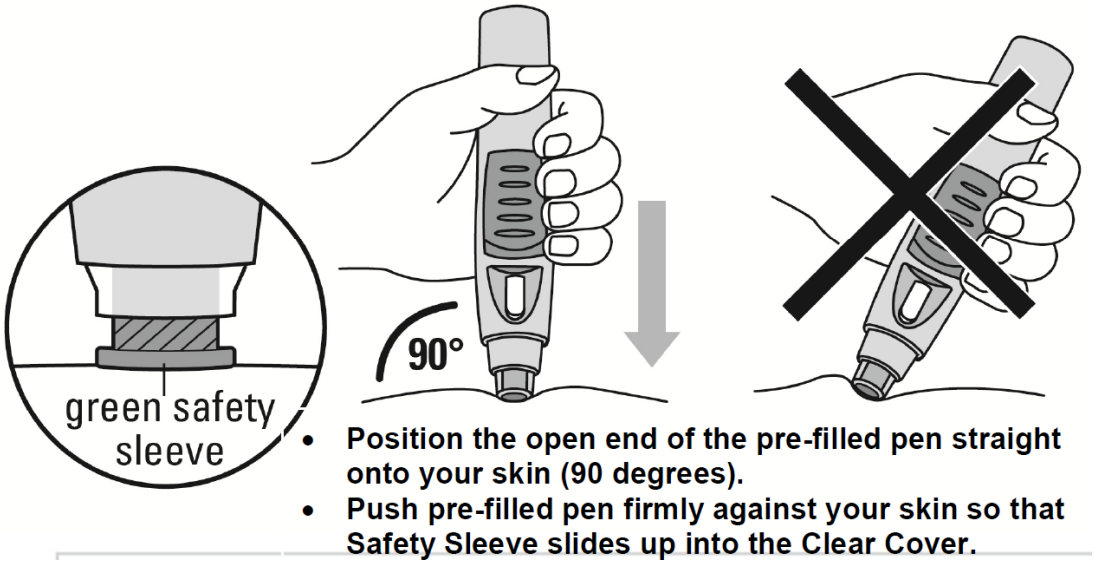
Do **NOT** put the cap back on because it may damage the needle inside the autoinjector.

Note: Do not use autoinjector if it is dropped without the cap in place. If you drop the autoinjector without the cap in place, please contact your doctor or pharmacist.

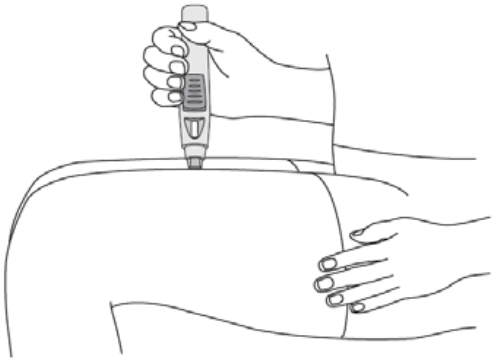
Push the Autoinjector against the skin

- Hold the autoinjector comfortably in your hand. **DO NOT** press the button at this time.
- Push the open end of the autoinjector firmly against the skin at a 90-degree angle.
- Do **NOT** pinch the skin.

- Do **NOT** press the button until **after** the autoinjector is pushed firmly against the skin and the Safety Sleeve slides fully into the Clear Cover.



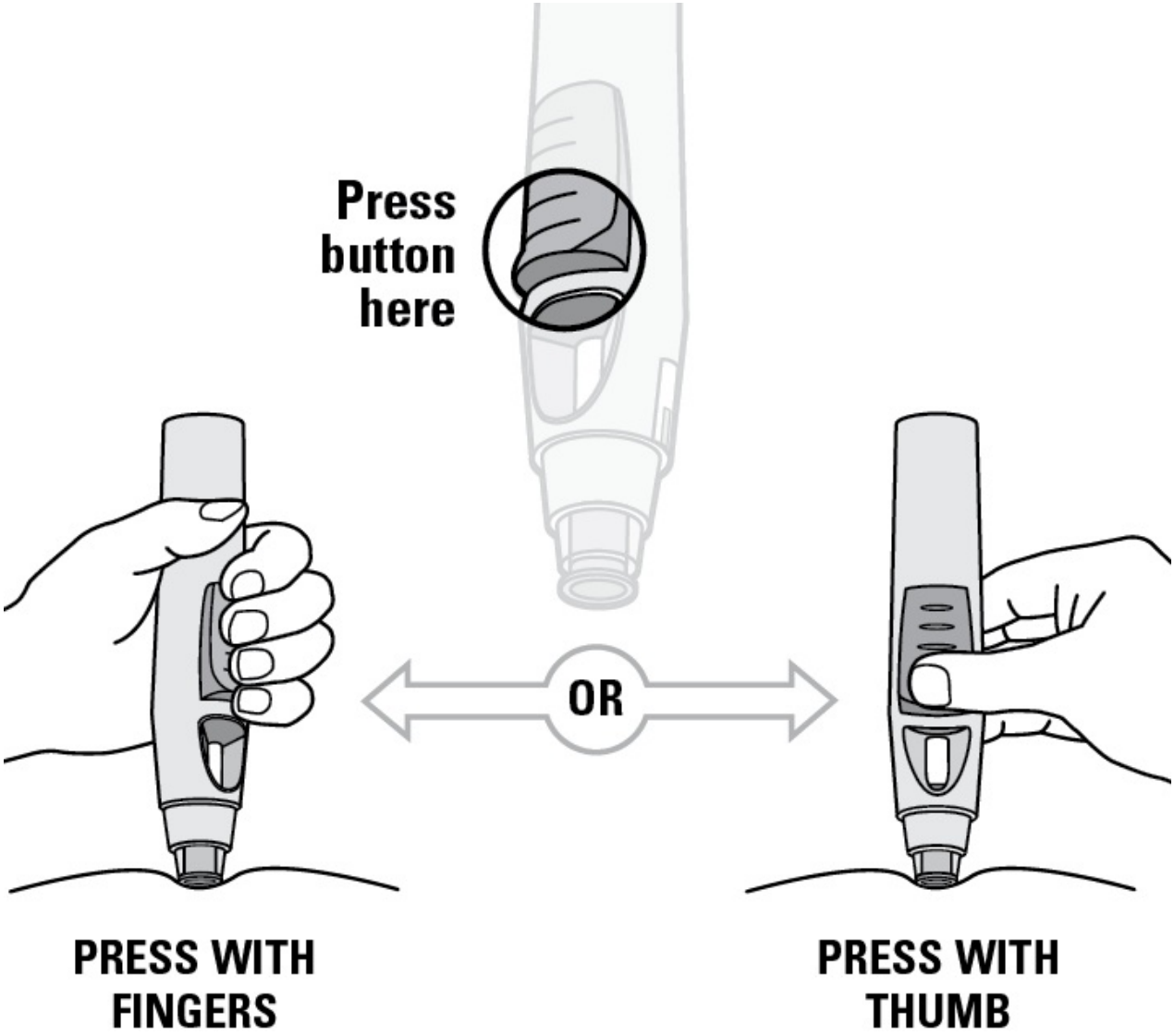
- Inject without pinching the skin.



Press Button to Inject

- **Continue to hold the autoinjector firmly against the skin, and press the front raised part of the button with your fingers or thumb**. You will not be able to press in the button unless the autoinjector is pushed firmly against your skin and the Safety Sleeve slides into the Clear Cover.

- Once the button is pressed, it will remain pressed in so you do not need to keep pressure on it.

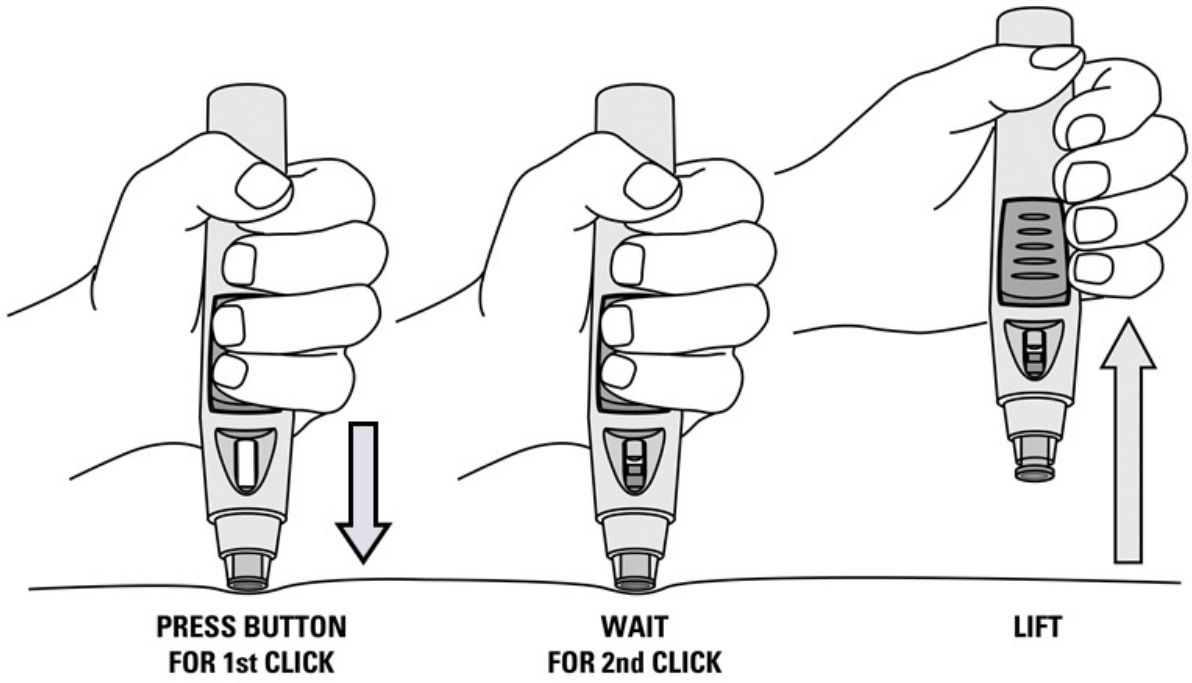


- **You will hear a loud ‘click’ sound – don’t be alarmed**. The first loud 'click' indicates that the needle has been inserted and the injection has started. You may or may not feel a needle prick at this time.

DO NOT lift the autoinjector away from your skin. If you pull the autoinjector away from the skin, you may not get your full dose of SIMPONI.

Wait for Second "Click"

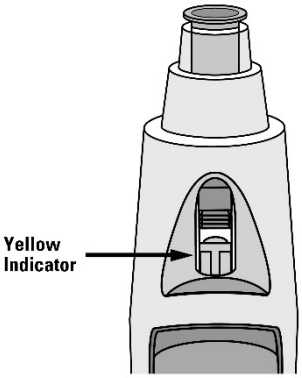
- **Continue to hold the autoinjector against the skin until you hear the second 'click' (it usually takes about 3 to 6 seconds, but may take up to 15 seconds for you to hear the second 'click' sound)**
- The second click indicates that the injection is finished and the needle has retracted into the autoinjector. **Note**: If you have a hearing problem and do not hear the second "click", count 15 seconds from the time you first press the button and then lift the autoinjector from the injection site.
- Lift the autoinjector from the injection site



STEP 4: AFTER THE INJECTION

Check the Viewing Window

- After injecting, check the viewing window to make sure that the yellow indicator is visible
- The yellow indicator may not fill the entire viewing window. This is normal.
- This indicates that the autoinjector has worked properly
- If you do not think you received your injection, check the yellow indicator again to confirm that the dose was delivered.
- If the yellow indicator is not visible in the viewing window, call your doctor for assistance. Do **NOT** administer a second dose without speaking to your doctor.



Disposing of the Autoinjector

- Immediately dispose of the autoinjector in the sharps container
- Dispose of the sharps container according to your local regulations when the container is full



Use Cotton Ball or Gauze

- There may be a small amount of blood or liquid at the injection site, which is normal
- You can press a cotton ball or gauze over the injection site for 10 seconds

Do **NOT** rub the injection site.

- You may cover the injection site with a small adhesive bandage, if necessary.