# PROPOSED CLEAN PATIENT INFORMATION LEAFLET (PIL)

**SCHEDULING STATUS**

Schedule 4

**SIMPONI® 45 mg/0,45 mL**

**Solution for injection in pre-filled pen**

**Golimumab**

**Contains sugar (sorbitol)**

**Each pre-filled pen contains 18,45 mg sorbitol (E420) per 45 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'. It is used **in children** 2 years of age and older for the treatment of polyarticular juvenile idiopathic arthritis.

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.

### Polyarticular juvenile idiopathic arthritis

Polyarticular juvenile idiopathic arthritis is an inflammatory disease that causes joint pain and swelling in children. If you have polyarticular juvenile idiopathic arthritis you 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.

### How much SIMPONI is given

Polyarticular juvenile idiopathic arthritis in children 2 years of age and older:

- Children weighing *less than 40 kg*:

  The recommended dose of SIMPONI for children weighing less than 40 kg depends on their weight and height. Your doctor will tell you the correct dose to use. The dose should be given once a month, on the same date each month.

- Children weighing *at least 40 kg*:

  For children with body weight of at least 40 kg, a fixed dose 50 mg pre-filled pen or pre-filled syringe is available. For the 50 mg dose, see section 3 “How to use

SIMPONI" of the SIMPONI 50 mg pre-filled pen or pre-filled syringe patient information leaflet.

- Talk to your doctor before you take the fourth dose. Your doctor will determine if you should continue SIMPONI treatment.

**How SIMPONI is given**

- SIMPONI is given by injection under the skin (subcutaneously).
- At the start, your doctor or nurse may inject SIMPONI. However, you and your doctor may decide that you may inject SIMPONI to yourself or to your child. In this case you will get training on how to inject SIMPONI.

Talk to your doctor if you have any questions about giving yourself an injection. You will find detailed "Instructions for Use" included with this leaflet.

**If you use more SIMPONI than you should**

If you have used or been given too much SIMPONI (either by injecting too much on a single occasion, or by using it too often), talk to your doctor or pharmacist straight away. 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, contact the nearest hospital or poison centre.

## If you forget to use SIMPONI

If you forget to use SIMPONI on your planned date, inject the forgotten dose as soon as you remember.

Do not use a double dose to make up for a forgotten dose.

When to inject your next dose:

- If you are less than 2 weeks late, inject the forgotten dose as soon as you remember and stay on your original schedule.
- If you are more than 2 weeks late, inject the forgotten dose as soon as you remember and talk to your doctor or pharmacist to ask when you need to take the next dose.

If you are not sure what to do, talk to your doctor or pharmacist.

## If you stop using SIMPONI

If you are considering stopping SIMPONI, talk to your doctor or pharmacist first.

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

## 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
- 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
- Blood clots
- Flushing
- Constipation
- Chronic inflammatory condition of the lungs
- Acid reflux
- 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)

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.
- Do not use this medicine after the expiry date which is stated on the label and the carton 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 pen in the outer carton in order to protect it from light.
- SIMPONI can also be stored out of the refrigerator at temperatures up to a maximum of 25 °C for a single period of up to 30 days, but not beyond the original expiry date printed on the carton. Write the new expiry date on the carton including day/month/year (no more than 30 days after the medicine is removed from the refrigerator). Do not return this medicine to refrigerator if it has reached room temperature. Discard this medicine if not used by the new expiry date or the expiry date printed on the carton, whichever is earlier.
- Do not use this medicine if you notice that the liquid is not a clear to light yellow colour, cloudy, or contains foreign particles.

- 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 0,45 mL pre-filled pen contains 45 mg of golimumab. 1 mL contains 100 mg 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 as solution for injection in a single-use pre-filled pen, VarioJect. SIMPONI is available in packs containing 1 pre-filled pen.

The solution is clear to slightly opalescent (having a pearl-like shine), colourless to light yellow and may contain a few small translucent or white particles of protein. Do not use SIMPONI if the solution is discoloured, cloudy or you can see foreign particles in it.

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## Holder of certificate of registration




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## Access to the corresponding Professional Information:

Included in the carton, accompanying this patient information leaflet.

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## Instructions for Use

## SIMPONI 45 mg/0,45 mL

Solution for injection in pre-filled pen, VarioJect

For paediatric use

**SINGLE-USE**




### Know your dose

Use the space above to record your prescribed dose.

Confirm with your doctor if you are unsure of your dose.

### Important

If your doctor decides that you or a caregiver may be able to give your injections of SIMPONI at home, you should receive training on the right way to prepare and inject SIMPONI.

Please read this Instructions for Use before using the SIMPONI pre-filled pen and each time you get a new pre-filled pen. There may be new information.

Please also read the 'Patient Information Leaflet' carefully before starting your injection. This instruction guide does not take the place of talking with your doctor about your medical condition or your treatment.

If you have not been trained, or have any questions, please contact your doctor, nurse or pharmacist.



**Storage information**

Store in refrigerator at 2° to 8°C.

Can be stored at room temperature (up to 25 °C) for a single period up to 30 days, but not exceeding the original expiry date. Write the new expiry date on the back panel of the carton including day/month/year (no more than 30 days after the medicine is removed from the refrigerator). Do not return this medicine to refrigerator if it has reached room temperature.

**Keep SIMPONI pre-filled pen and all medicines out of the sight and reach of children.**

## Overview

The pre-filled pen is a **manual** injection pen that allows you to set a specific, prescribed dose. Each pre-filled pen can deliver 0,1 mL to 0,45 mL (corresponding to 10 mg to 45 mg golimumab) in increments of 0,05 mL.

Before you begin using this pre-filled pen, you should know how to:

- Remove air bubbles
- Set prescribed dose
- **Manually press the plunger** to inject, like a syringe

The pre-filled pen is to be used only one time. Dispose of the pre-filled pen after use.

**Do not** attempt to use any leftover medicine in the pre-filled pen.

**Do not** share the pre-filled pen with anyone.

**Do not** shake.

## Need help?

Call your doctor, nurse or pharmacist to talk about any questions you may have. For additional assistance refer to the Patient Information Leaflet for your local representative contact information.

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## Plan ahead



### Inspect carton

**Check the expiration date ('EXP')** printed or written on the back panel of the carton.

**Do not** use if the expiration date has passed.

**Do not** inject if the perforations on the carton are broken. Call your doctor or pharmacist for a new pre-filled pen.



### Remove the pre-filled pen from the carton

Let the pre-filled pen sit **at room temperature for at least 30 minutes** out of reach of children.

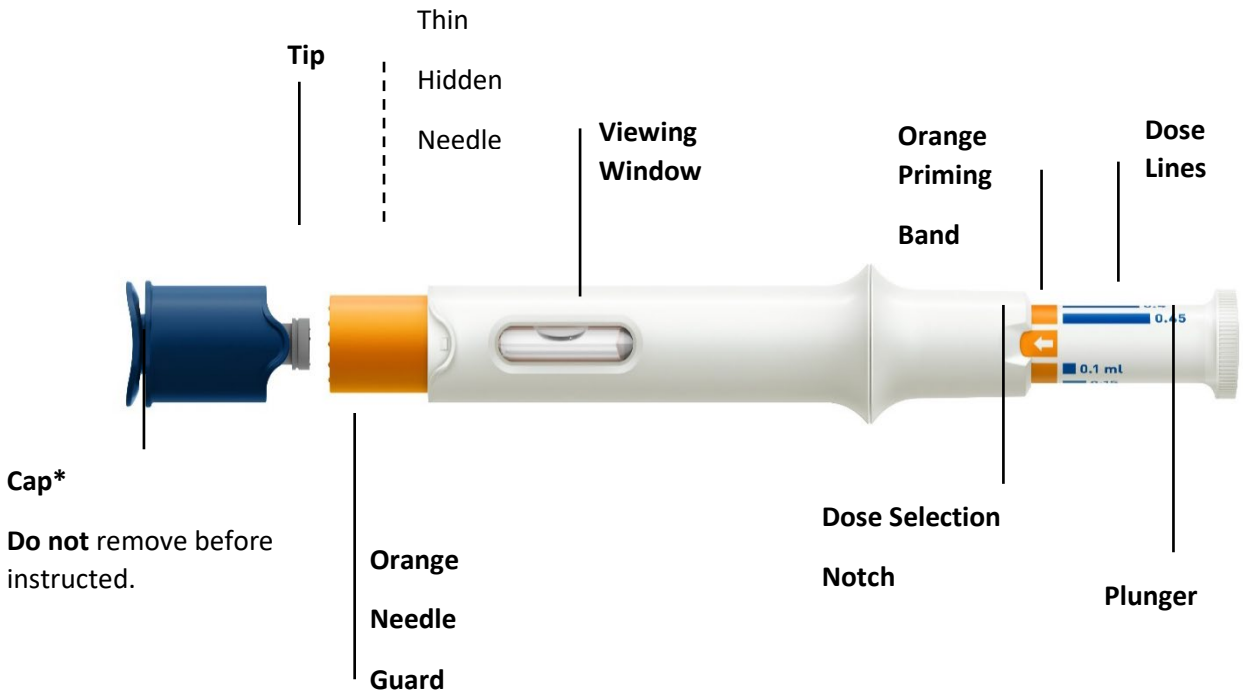
**Do not** warm any other way.

### You will need these supplies:

- **1 Alcohol swab**
- **1 Cotton ball** or **gauze pad**
- **1 Adhesive bandage**
- **1 Sharps container** (See Step 3)

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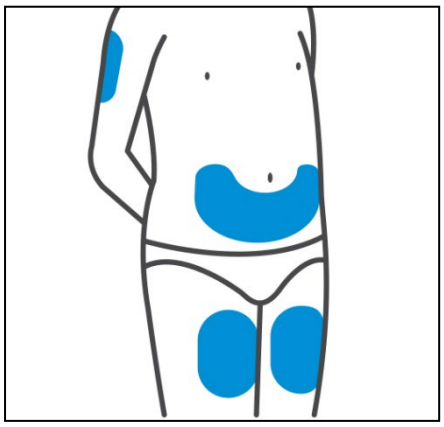
## Your pre-filled pen at-a-glance




**IMPORTANT:**
**Do not** press on the orange needle guard before the injection. It will lock, and you will not receive the dose.
**Do not** lift the pre-filled pen from the skin during the injection. The orange needle guard will lock, and you will not receive the full dose.

*CHOKING HAZARD! Keep out of reach of children.

## 1. Prepare for your injection



## Choose injection site

Select from the following areas for your injection:

- **Front of thighs** (recommended)
- Lower abdomen

  **Do not** use the 5-centimetre area around your belly-button.

- Back of upper arms (if a caregiver is giving you the injection)

Choose a different site within your preferred area for each injection.

**Do not** inject into skin that is tender, bruised, red, scaly, hard or has scars.

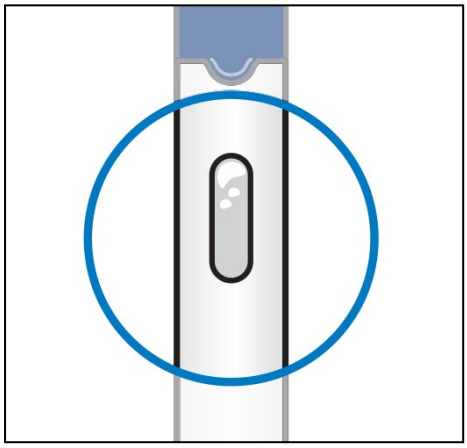


### Clean injection site

Wash your hands well with soap and warm water.

Wipe your chosen injection site with an alcohol swab and allow it to dry.

**Do not** touch, fan, or blow on the injection site after you have cleaned it.

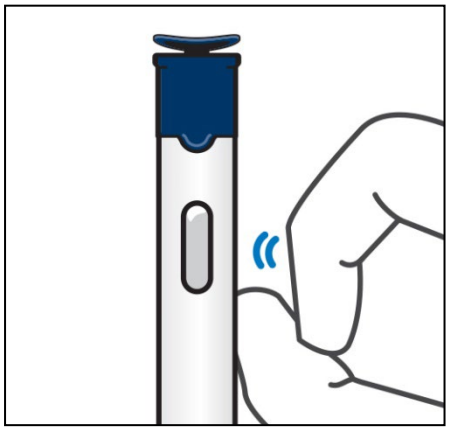


### Inspect liquid

Take the pre-filled pen out of the carton.

Check the liquid in the viewing window. It should be clear to slightly opalescent (having pearl-like shine) and colourless to light yellow and may contain a few small translucent or white particles of protein. You may also see one or more air bubbles. This is normal.

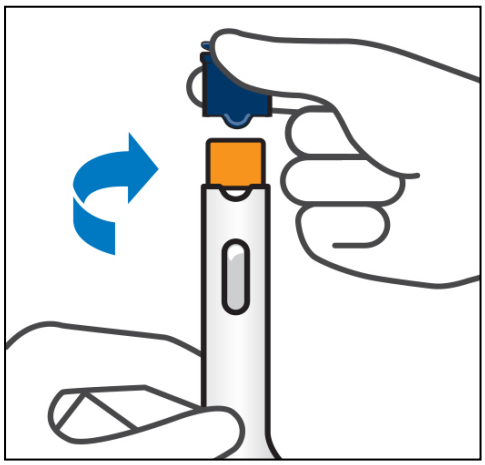
**Do not** inject if the liquid is the wrong colour, cloudy or has large particles. If you are uncertain, call your doctor or pharmacist for a new pre-filled pen.



**Tap air bubbles to top**

Hold the pre-filled pen upright with the blue cap pointing up.

Tap the pre-filled pen gently with your finger near the viewing window. This will cause any air bubbles to rise to the top.



**Remove cap**

Keep holding the pre-filled pen upright, then twist and pull the cap to remove.

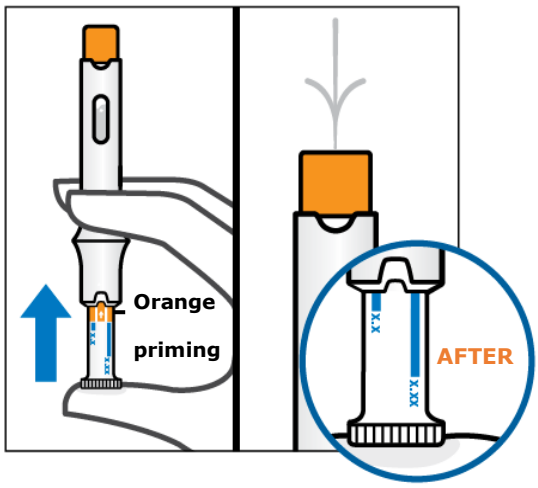
**IMPORTANT: Do not** press on the orange needle guard before the injection. It will lock, and you will not receive the dose.

**Inject within 5 minutes of removing the cap.**

**Do not** put the cap back on, this may damage the hidden needle.

**Do not** use the pre-filled pen if it is dropped without the cap on.

Call your doctor or pharmacist for a new pre-filled pen.




**Remove air bubbles***

Keep holding the pre-filled pen upright.

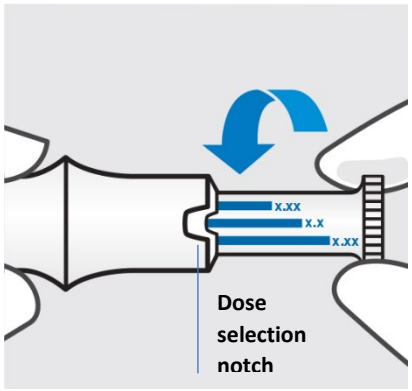
Gently, press the plunger up with your thumb until it stops. Liquid will squirt out. This is normal.

**The orange priming band will disappear.**

**Removing air bubbles helps make sure the right dose is given.*

*After you remove the air bubbles, you may see a line inside the viewing window. This is normal.*

## 2. Inject SIMPONI using the pre-filled pen




### Set prescribed dose

Turn plunger until the dose line for your prescribed dose lines up with the dose selection notch. The pre-filled pen is now ready to use.

### Dose selections:

0,1 mL

0,15 mL

0,2 mL

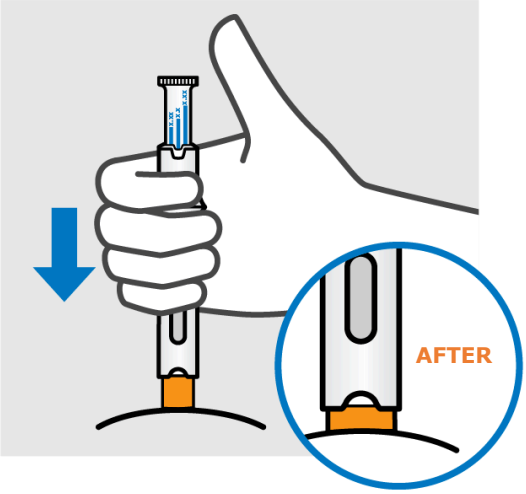
0,25 mL

0,3 mL

0,35 mL

0,4 mL

0,45 mL

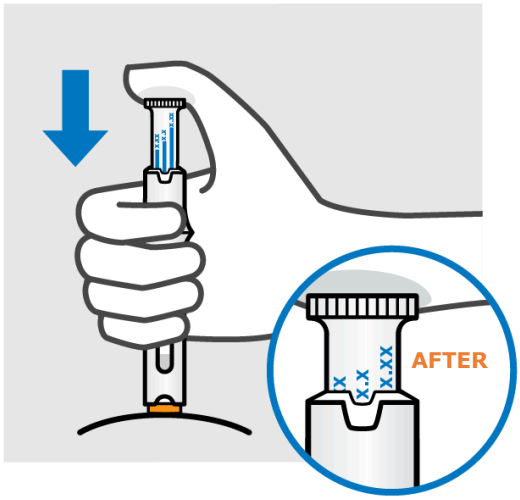



**Insert needle and hold in place**

**IMPORTANT: Do not** lift the pre-filled pen from the skin during the injection. The orange needle guard will lock, and you will not receive the full dose.

**Do not** press the plunger while inserting the needle.

Push and hold the pre-filled pen tip against the skin so the orange needle guard pushes up until it stops. Some orange will still be showing.




**Inject SIMPONI**

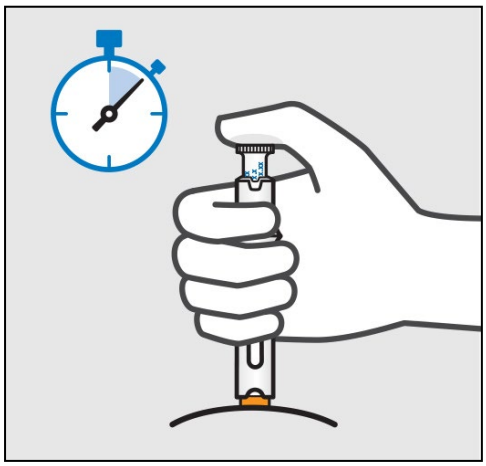
Keep pushing the pre-filled pen against the skin.

Gently, press the plunger until it stops.

**If a small dose is set, the plunger will only move a short distance.**

The dose you delivered can be confirmed by viewing the dose selection notch.

**Do not** lift the pre-filled pen up yet.



**Keep holding, then lift**

Keep pushing the pre-filled pen against the skin for approximately 5 seconds.

It is normal to see some drug still visible in the viewing window.

Lift the pre-filled pen away from the skin.

The orange needle guard will extend and lock.

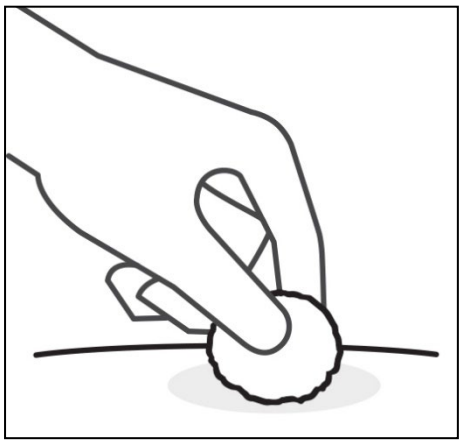
## 3. After your injection



### Throw the used pre-filled pen away

Put your used pre-filled pen in a sharps disposal container right away after use.

Make sure you dispose of the bin as instructed by your doctor or nurse when the container is full.



### Check injection site

There may be a small amount of blood or liquid at the injection site.

Hold pressure on your skin with a cotton ball or gauze pad until any bleeding stops.

**Do not** rub the injection site.

If needed, cover injection site with a bandage. Your injection is now complete!