

## **Package Leaflet: Information for the user**

### **Simponi 45 mg/0.45 mL solution for injection in pre-filled pen**

For paediatric patients below 40 kg  
golimumab

**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, 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 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- $\alpha$ ). 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 you do not respond well enough to these medicines, you 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 allergic (hypersensitive) to golimumab or any of the other ingredients of this medicine (listed in Section 6).
- If you have tuberculosis (TB) or any other severe infection.
- If you have moderate or severe heart failure.

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**

Talk to your doctor, pharmacist or nurse before using Simponi.

### Infections

Tell your doctor straight away if you already have or get any symptoms of infection, during or after your treatment with Simponi. Symptoms of infection include fever, cough, shortness of breath, flu-like symptoms, diarrhoea, wounds, dental problems or a burning feeling when urinating.

- You may get infections more easily while using Simponi.
- Infections may progress more rapidly and may be more severe. In addition, some previous infections may reappear.

#### *Tuberculosis (TB)*

Tell your doctor straight away if symptoms of TB appear during or after your treatment. Symptoms of TB include persistent cough, weight loss, tiredness, fever or night sweats.

- Cases of TB have been reported in patients treated with Simponi, in rare occasions even in patients who have been treated with medicines for TB. Your doctor will test you to see if you have TB.
- It is very important that you tell your doctor if you have ever had TB, or if you have been in close contact with someone who has had or has TB.
- If your doctor feels that you are at risk of TB, you may be treated with medicines for TB before you begin using Simponi.

#### *Hepatitis B virus (HBV)*

- Tell your doctor if you are a carrier or if you have or have had HBV before you are given Simponi.
- Tell your doctor if you think you might be at risk of contracting HBV.
- Your doctor should test you for HBV.
- Treatment with TNF blockers such as Simponi may result in reactivation of HBV in patients who carry this virus, which can be life-threatening in some cases.

#### *Invasive fungal infections*

If you have lived in or travelled to an area where infections caused by specific type of fungi that can affect the lungs or other parts of the body (called histoplasmosis, coccidioidomycosis, or blastomycosis), are common, tell your doctor straight away. Ask your doctor if you don't know if these fungal infections are common in the area in which you have lived or travelled.

### Cancer and lymphoma

Tell your doctor if you have ever been diagnosed with lymphoma (a type of blood cancer) or any other cancer before you use Simponi.

- If you use Simponi or other TNF-blockers, your risk for developing lymphoma or another cancer may increase.
- Patients with severe rheumatoid arthritis and other inflammatory diseases, who have had the disease for a long time, may be at higher than average risk of developing lymphoma.
- There have been cases of cancers, including unusual types, in children and teenage patients taking TNF-blocking agents, which sometimes resulted in death.
- On rare occasions, a specific and severe type of lymphoma called hepatosplenic T-cell lymphoma has been observed in patients taking other TNF-blockers. Most of these patients were adolescent or young adult males. This type of cancer has usually resulted in death. Almost all of these patients had also received medicines known as azathioprine or 6-mercaptopurine. Tell your doctor if you are taking azathioprine or 6mercaptopurine with Simponi.
- Patients with severe persistent asthma, chronic obstructive pulmonary disease (COPD), or are heavy smokers may be at increased risk for cancer with Simponi treatment. If you have severe persistent asthma, COPD or are a heavy smoker, you should discuss with your doctor whether treatment with a TNF-blocker is appropriate for you.

- Some patients treated with golimumab have developed certain kinds of skin cancer. If any changes in the appearance of the skin or growths on the skin occur during or after therapy, tell your doctor.

#### Heart failure

Tell your doctor straight away if you get new or worsening symptoms of heart failure. Symptoms of heart failure include shortness of breath or swelling of your feet.

- New and worsening congestive heart failure has been reported with TNF-blockers, including Simponi. Some of these patients died.
- If you have mild heart failure and you are being treated with Simponi, you must be closely monitored by your doctor.

#### Nervous system disease

Tell your doctor straight away if you have ever been diagnosed with or develop symptoms of a demyelinating disease such as multiple sclerosis. Symptoms may include changes in your vision, weakness in your arms or legs or numbness or tingling in any part of your body. Your doctor will decide if you should receive Simponi.

#### 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 Simponi.

#### Autoimmune disease

Tell your doctor if you develop symptoms of a disease called lupus. Symptoms include persistent rash, fever, joint pain and tiredness.

- On rare occasions, people treated with TNF-blockers have developed lupus.

#### Blood disease

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 right away. Your doctor may decide to stop treatment.

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

#### 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 Simponi.
- Certain vaccinations may cause infections. If you received Simponi while you were pregnant, your baby may be at higher risk for getting such an infection for up to approximately six 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 Simponi use so they can decide when your baby should receive any vaccine.

Talk to your child's doctor regarding vaccinations for your child. If possible, your child should be up to date with all vaccinations before using Simponi.

#### Therapeutic infectious agents

Talk to your doctor if you have recently received or are scheduled to receive treatment with a therapeutic infectious agent (such as BCG instillation used for the treatment of cancer).

### Allergic reactions

Tell your doctor straight away if you develop symptoms of an allergic reaction after your treatment with Simponi. 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 may be serious or, rarely, life-threatening.
- Some of these reactions occurred after the first administration of Simponi.

### **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**

- Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including any other medicines to treat polyarticular juvenile idiopathic arthritis.
- You should not take Simponi with medicines containing the active substance anakinra or abatacept. These medicines are used for the treatment of rheumatic diseases.
- 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.

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

### **Pregnancy and breast-feeding**

Talk to your doctor before using Simponi if:

- You are pregnant or are planning to become pregnant while using Simponi. The effects of this medicine in pregnant women are not known. The use of Simponi in pregnant women is not recommended. If you are being treated with Simponi, you must avoid becoming pregnant by using adequate contraception during your treatment and for at least 6 months after the last Simponi injection.
- Before starting breast-feeding, your last treatment with Simponi must be at least 6 months ago. You must stop breast-feeding if you are to be given Simponi.
- If you received Simponi 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 Simponi use before the baby receives any vaccine (for more information see section on vaccination).

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.

### **Driving and using machines**

Simponi has minor influence on your ability to ride bicycles, drive and use tools or machines. Dizziness may however occur after you take Simponi. If this happens, do not ride bicycles, drive or use any tools or machines.

### **Simponi contains latex and sorbitol**

#### 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 carer are allergic to latex.

#### Sorbitol intolerance

Simponi contains sorbitol (E420). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### **3. How to use Simponi**

Always use this medicine exactly as your doctor or pharmacist has told you. You should 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 package 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.

#### **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

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some patients may experience serious side effects and may require treatment. Side effects may appear up to several months after the last injection.

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 (rare).** 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) (common).** 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 (rare).** 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 (rare).** 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) (rare).** Symptoms of lymphoma can include swelling of the lymph nodes, weight loss, or fever.
- **heart failure (rare).** Symptoms of heart failure can include shortness of breath or swelling of your feet.
- **signs of immune system disorders called:**
  - **lupus (rare).** Symptoms can include joint pain or a rash on cheeks or arms that is sensitive to the sun.
  - **sarcoidosis (rare).** 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) (rare).** Symptoms can include fever, headache, weight loss, night sweats, rash, and nerve problems such as numbness and tingling.
- **skin cancer (uncommon).** Symptoms of skin cancer can include changes in the appearance of your skin or growths on your skin.
- **blood disease (common).** 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) (rare).** 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:**

##### Very common side effects (may affect more than 1 in 10 people):

- Upper respiratory tract infections, sore throat or hoarseness, runny nose

##### Common side effects (may affect up to 1 in 10 people):

- 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)
- 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

Uncommon side effects (may affect up to 1 in 100 people):

- 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

Rare side effects (may affect up to 1 in 1,000 people):

- 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 thread-like 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

Side effects of which the frequency is not known:

- A rare blood cancer affecting mostly young people (hepatosplenic T-cell lymphoma)

**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. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Simponi**

- 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 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 prefilled pen in the outer carton in order to protect it from light.
- This medicine 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.
- Do not throw away any medicines via wastewater or household waste. Ask your doctor or pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.



## **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.

### **Batch Releaser**

Cilag AG  
Hochstrasse 201  
8200 Schaffhausen  
Switzerland

### **Product Registrant**

Johnson & Johnson International (Singapore) Pte. Ltd.  
2 Science Park Drive  
#07-13, Ascent  
Singapore Science Park 1  
Singapore 118222

### **Last Revision of Text**

03 January 2023 (EU SmPC 23 August 2019)

## 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 'Package Leaflet: Information for the user' 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 Package Leaflet for your local representative contact information.

### **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**

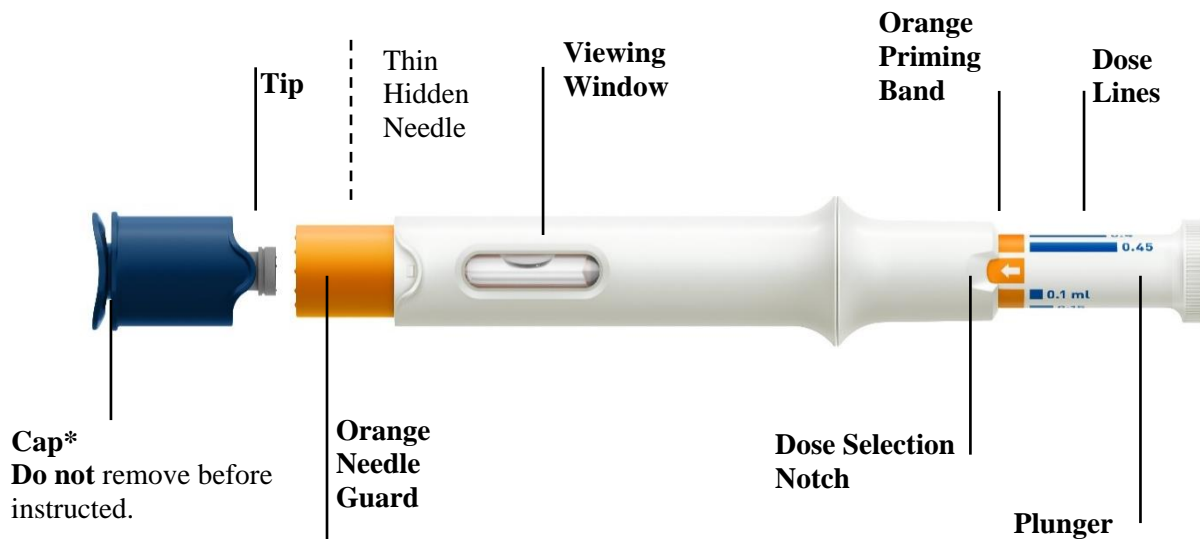
Let the pre-filled pen sit **at room temperature for at least 30 minutes** out of reach of children.

**Do not** warm any other way.

#### **You will need these supplies:**

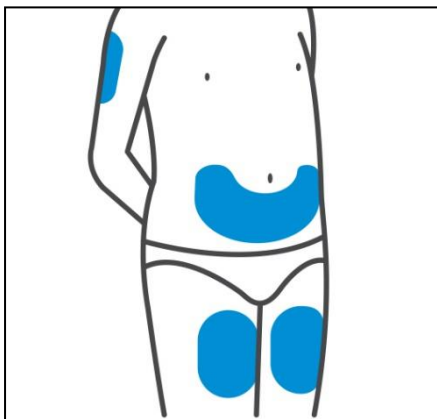
- **1 Alcohol swab**
- **1 Cotton ball or gauze pad**
- **1 Adhesive bandage**
- **1 Sharps container** (See Step 3)

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



\*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.

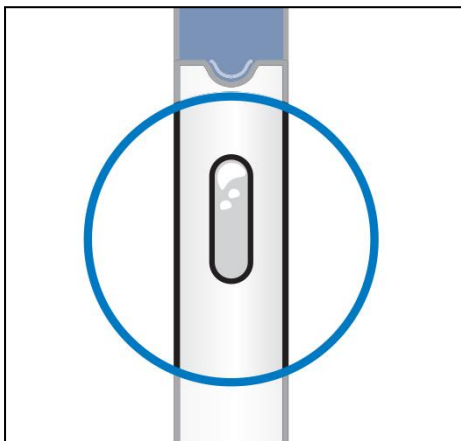


### **Clean injection site**

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.

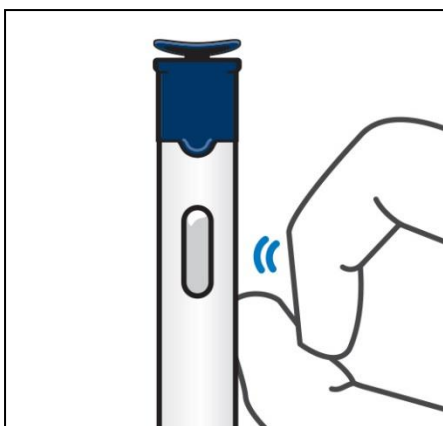


### **Inspect liquid**

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.

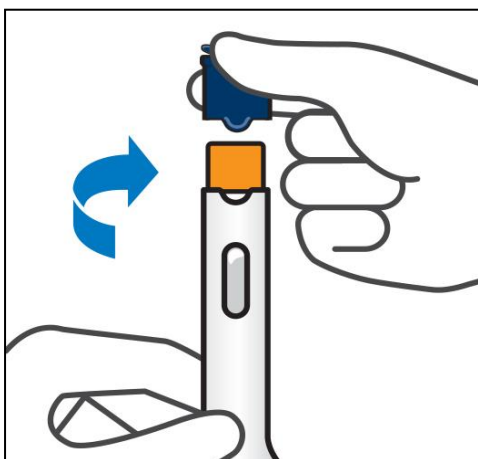
**Do not** inject if the liquid is the wrong colour, cloudy or has large particles. If you are uncertain, call your doctor or pharmacist for a new pre-filled pen.



### **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.

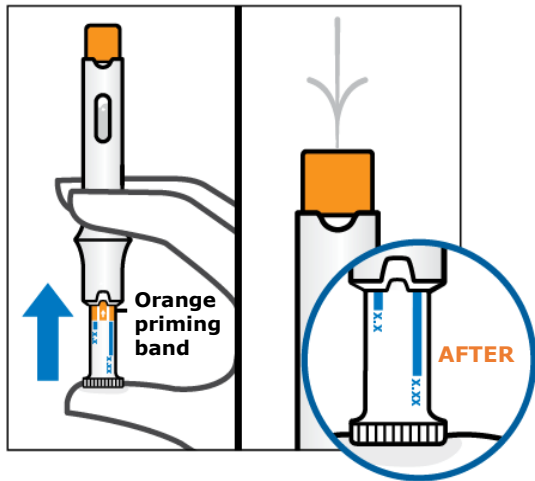
**IMPORTANT:** Do not press on the orange needle guard before the injection. It will lock, and you will not receive the dose.

### **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.

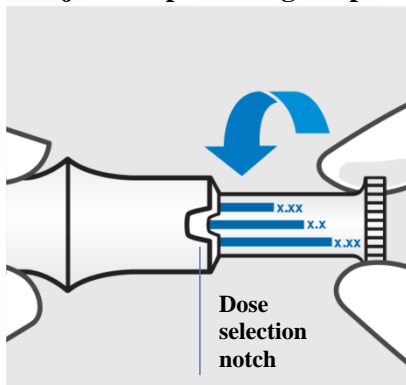
Gently, press the plunger up with your thumb until it stops. Liquid will squirt out. This is normal.

**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

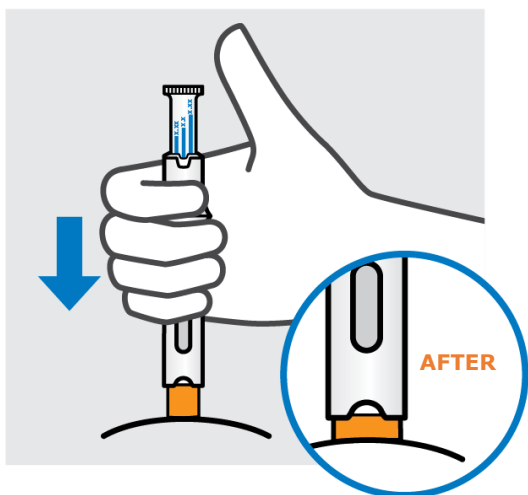
0.25 mL

0.3 mL

0.35 mL

0.4 mL

0.45 mL

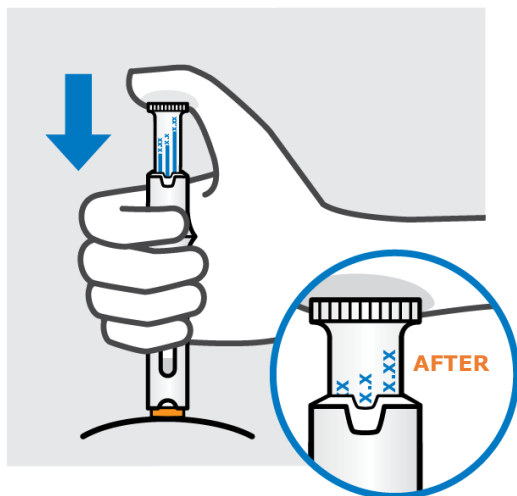


### Insert needle and hold in place

**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.

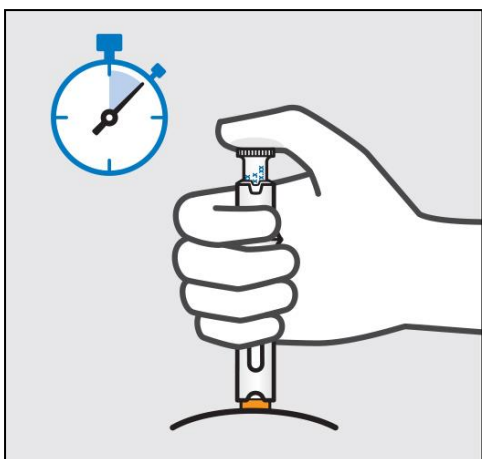
Gently, press the plunger until it stops.

**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**

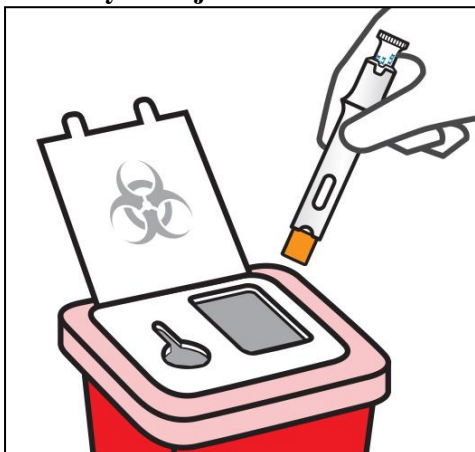
Keep pushing the pre-filled pen against the skin for approximately 5 seconds.

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.

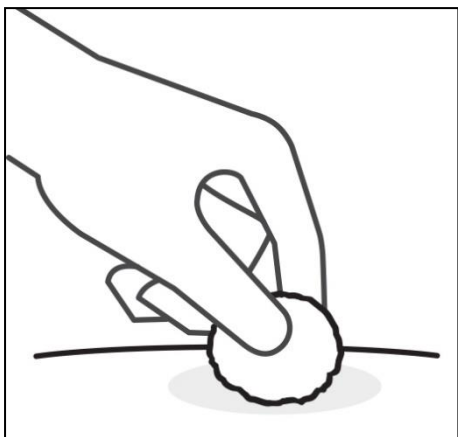
**3. After your injection**



**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!