

# SIMPONI<sup>®</sup> pre-filled syringe

*Golimumab (rmc)*

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## INSTRUCTIONS FOR USE

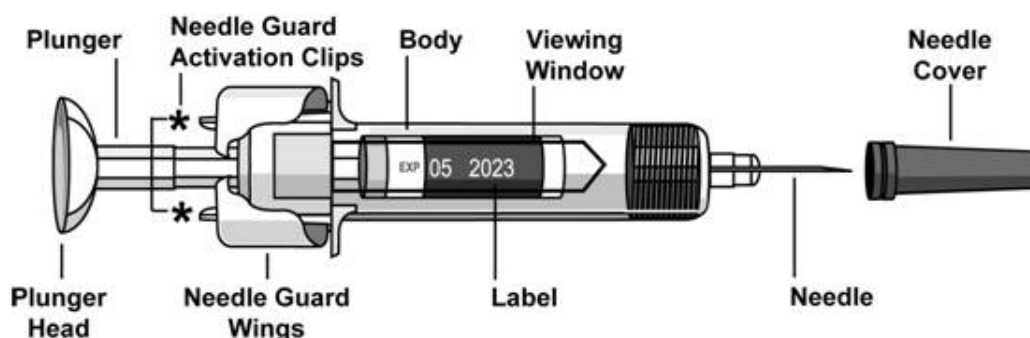
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### What is the SIMPONI pre-filled syringe

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SIMPONI pre-filled syringe is a single-use pre-filled syringe for subcutaneous injection. Each pre-filled syringe contains 50 mg or 100 mg of the active ingredient golimumab.



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### Before you use

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Please note the following important points before using SIMPONI pre-filled syringe:

- \* At the start of your therapy, your doctor or nurse may inject SIMPONI for you. However, you and your doctor can decide that you may inject SIMPONI yourself. If this is the case, you will receive training on how to inject SIMPONI yourself.
- \* **If you are injecting SIMPONI yourself, follow closely the instructions provided in the instruction leaflet inside your pack.**
- \* **Ask your doctor or nurse if you have any questions about SIMPONI or about giving yourself an injection.**
- \* **Nurse support is available by calling the Janssen Immunology Patient Support Program on 1800 666 845**
- \* **Read the Consumer Medicine Information (CMI) before you start using it**  
The SIMPONI CMI contains very useful information about SIMPONI, and is available from your pharmacist.
- \* **Keep SIMPONI in the outer carton until it is time to use it.**  
This helps protect it from light.
- \* **DO NOT shake the pre-filled syringe at any time.**
- \* **DO NOT remove the needle cover from the pre-filled syringe until instructed to do so.**
- \* **Keep SIMPONI in a refrigerator where the temperature stays between 2°C and 8°C, in a place where children cannot get to it. DO NOT freeze.**

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## How to use

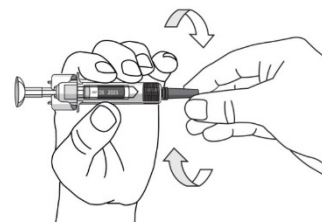
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### Step 1: Preparing to use the pre-filled syringe

1. Check the expiry date (as indicated by “EXP”) on the label by looking through the viewing window located within the body of the pre-filled syringe

If you cannot see the expiry date through the viewing window, hold the pre-filled syringe by its body and rotate the needle cover to line up the expiry date to the viewing window.

You can also check the expiry date printed on the carton.



If the expiry date has passed, or if the pre-filled syringe has been kept at room temperature (up to 25°C) for longer than 30 days or if the pre-filled syringe has been stored above 25°C, DO NOT use the pre-filled syringe and contact your doctor or pharmacist.

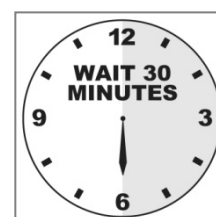
- \* Hold the pre-filled syringe by the body of the syringe.
- \* DO NOT shake the pre-filled syringe.
- \* DO NOT remove the needle cover from the pre-filled syringe at this point.
- \* DO NOT touch the needle guard activation clips (as indicated by asterisks \* in the first illustration) to prevent prematurely covering the needle with the needle guard.

2. Wait for 30 minutes

- \* take the pre-filled syringe out of the carton and allow to sit at room temperature for 30 minutes.

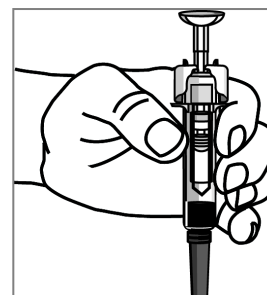
To ensure proper injection, the pre-filled syringe should be allowed to reach room temperature.

- \* DO NOT warm the pre-filled syringe in any other way.  
For example, do not warm it in a microwave or in hot water.
- \* DO NOT expose pre-filled syringe to direct sunlight.
- \* DO NOT remove the needle cover of the syringe while allowing it to reach room temperature.
- \* always keep the pre-filled syringe where children cannot reach it.



3. 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 for syringe disposal.



4. Check the solution in the pre-filled syringe by looking through the viewing window

- \* hold the pre-filled syringe with the covered needle pointing down.

The solution in the pre-filled syringe should be clear to slightly opalescent and colourless to light yellow. It may contain a few tiny particles that are white, or that you can see through. You may also notice an air bubble, which is normal.

- \* DO NOT use it if the solution is discoloured or cloudy, or has large particles in it.

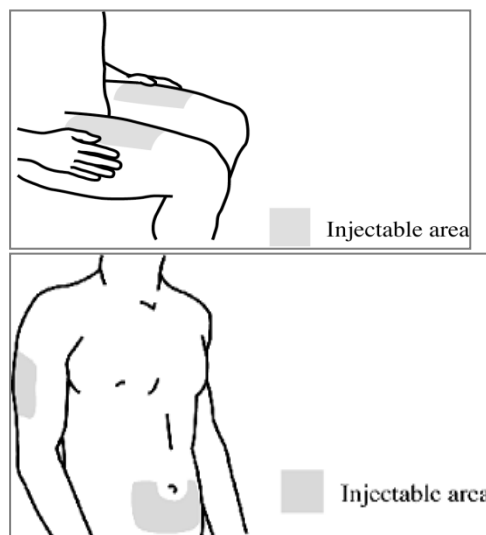
If it is discoloured or cloudy, or has large particles, please contact your doctor or pharmacist.

## Step 2: Choosing and preparing the injection site

### 1. Choose the injection site.

The recommended injection site is the front of the middle thighs. You can also use the lower part of the abdomen, below the belly button, except for the 5-centimetre area directly underneath the belly button. If a caregiver is giving you the injection, the caregiver can also use the outer area of the upper arms.

- \* rotate injection sites.
  - \* **DO NOT** inject into areas where the skin is tender, bruised, red, scaly or hard.
  - \* avoid areas with scars or stretch marks.
- ### 2. Preparing the injection site.
- \* wash your hands thoroughly with soap and warm water.
  - \* wipe the injection site with an alcohol swab and **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

- \* **DO NOT** remove the needle cover until you are ready to inject SIMPONI.  
SIMPONI should be injected within 5 minutes after the cover has been removed.

### 1. Remove the needle cover

**DO NOT** touch the plunger during needle cover removal.

- \* when you are ready to inject, remove the needle cover by holding the body of the syringe with one hand and pulling the needle cover straight off.

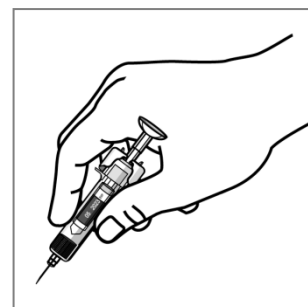
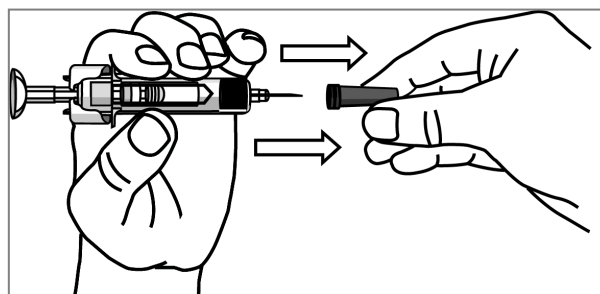
You may notice a small air bubble in the pre-filled syringe. You **DO NOT** need to remove the air bubble. You may also see a drop of liquid at the end of the needle – this is normal.

- \* throw the needle cover into the trash.
- \* **DO NOT** touch the plunger.
- \* **DO NOT** touch the needle.
- \* **DO NOT** drop the pre-filled syringe.

If the pre-filled syringe is dropped without the needle cover in place, it should **NOT** be used. If you drop the pre-filled syringe without the needle cover in place, please contact your doctor or pharmacist.

### 2. Position the pre-filled syringe

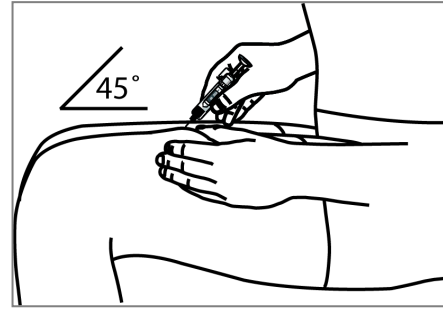
- \* hold the body of the pre-filled syringe in one hand like a pencil, between the thumb and index fingers and place the thumb on top of the plunger head.
- \* **DO NOT** pull back on the plunger at any time



- \* use the other hand to gently pinch the area of skin that you previously cleaned. Hold firmly.

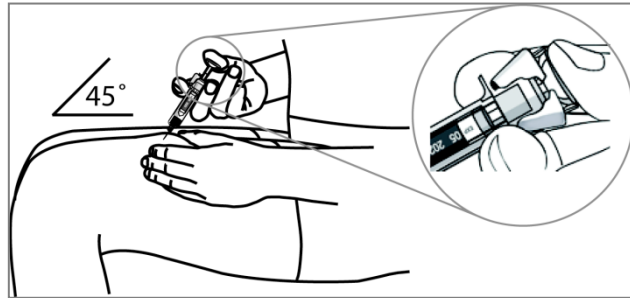
### 3. Inject the medicine

- \* use a quick, dart-like motion to insert the needle into the pinched skin at a 45-degree angle.  
The needle should be inserted through the skin as far as it will go.

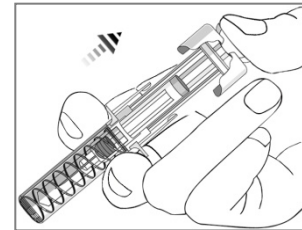


- \* to inject the medicine, push in the plunger until the plunger head is completely between the needle guard wings.

When the plunger meets the end of the syringe barrel, all of the medication has been injected.



- \* whilst keeping pressure on the plunger head, take the needle out of the skin and let go of the skin.
- \* slowly take your thumb off the plunger head.  
This will let the empty syringe move up until the entire needle is covered by the needle guard.



### Step 4: After the injection

#### 1. Dispose of the empty syringe.

- \* discard any unused product appropriately.  
This medicine is for single use in one patient only.
- \* **DO NOT attempt to recap the needle.**
- \* **DO NOT attempt to re-use the syringe or needle.**  
For your safety and health and for the safety of others, needles and syringes must never be re-used.
- \* **Put your used pre-filled syringe in a sharps disposal container right away after use.**
- \* **Do not throw away (dispose of) the pre-filled syringe in your household rubbish.**
- \* If you do not have a sharps disposal container, you may use a household container that is:
  - made of a heavy-duty plastic,
  - can be closed with a tightfitting, puncture-resistant lid, without sharps being able to come out,
  - upright and stable during use,
  - leak-resistant, and
  - properly labelled to warn of hazardous waste inside the container.
- \* **Do not recycle your used sharps disposal container.**



#### 2. Use cotton ball or gauze

There may be a small amount of blood or liquid at the injection site, which is normal.

- \* **press a cotton ball or gauze over the injection site for 10 seconds.**
- \* **DO NOT rub the injection site.**
- \* **if necessary, you may cover the injection site with a small adhesive plaster.**

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## **Further Information**

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### ***Sponsor***

In Australia SIMPONI is supplied by:  
JANSSEN-CILAG Pty Ltd  
1-5 Khartoum Road  
Macquarie Park NSW 2113 Australia  
Telephone: 1800 226 334

### ***Australian Registration Number***

SIMPONI 50 mg pre-filled syringe: AUST R 153767  
SIMPONI 100 mg pre-filled syringe: AUST R 208278

### ***Nurse and educational support***

The Janssen Immunology Patient Support Program is available to patients prescribed SIMPONI. **Call 1800 666 845**

### ***Date of Preparation***

April 2022