

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**

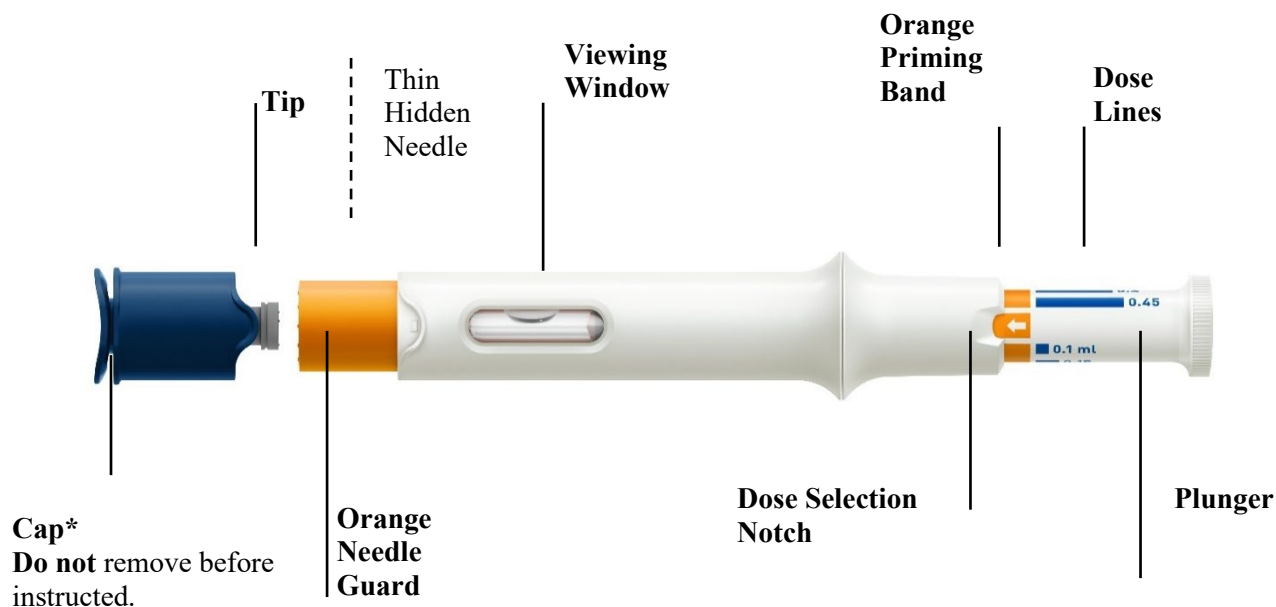
Let the pre-filled pen sit **at room temperature for at least 30 minutes** out of reach of children.

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



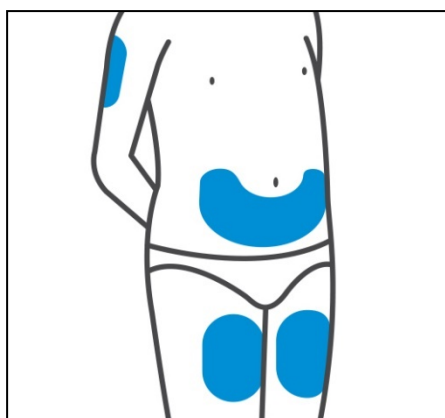
IMPORTANT:

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

*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.

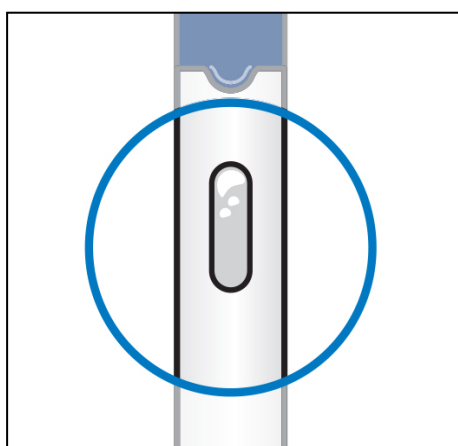


Clean injection site

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.

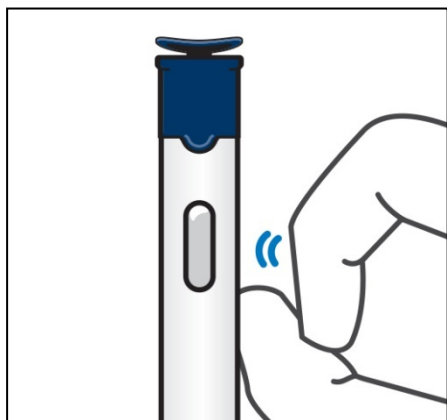


Inspect liquid

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.

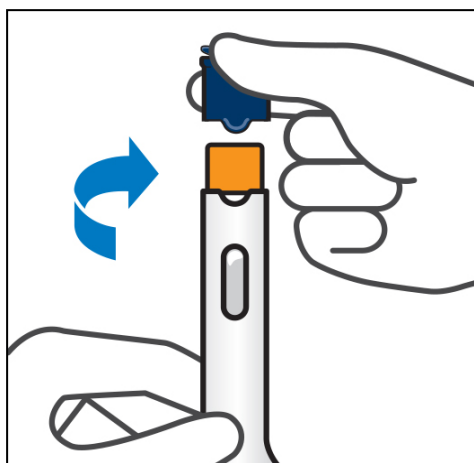
Do not inject if the liquid is the wrong colour, cloudy or has large particles. If you are uncertain, call your doctor or pharmacist for a new pre-filled pen.



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.

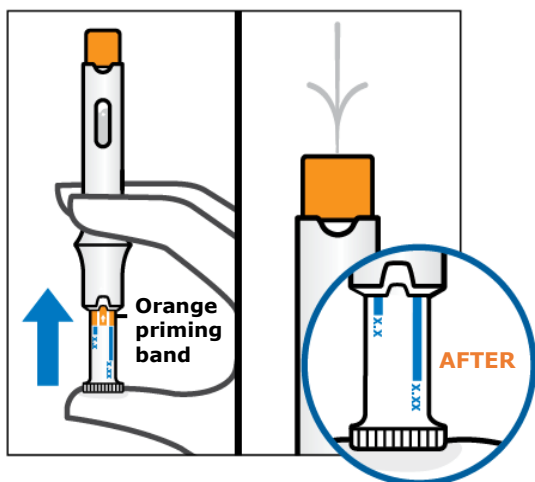
IMPORTANT: Do not press on the orange needle guard before the injection. It will lock, and you will not receive the dose.

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.

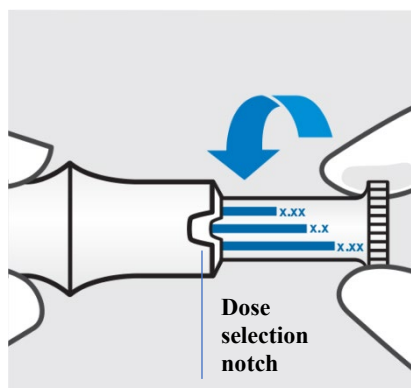
Gently, press the plunger up with your thumb until it stops. Liquid will squirt out. This is normal.

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

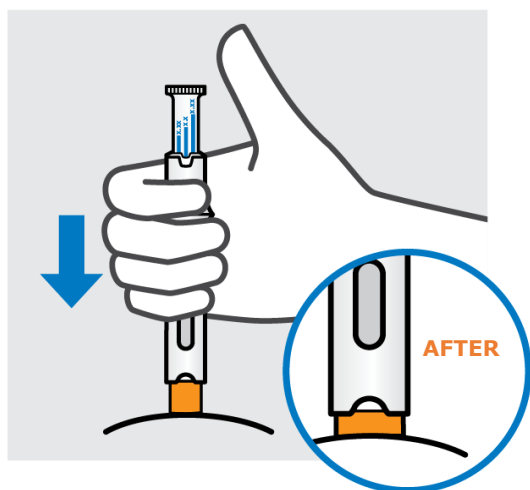
0.25 mL

0.3 mL

0.35 mL

0.4 mL

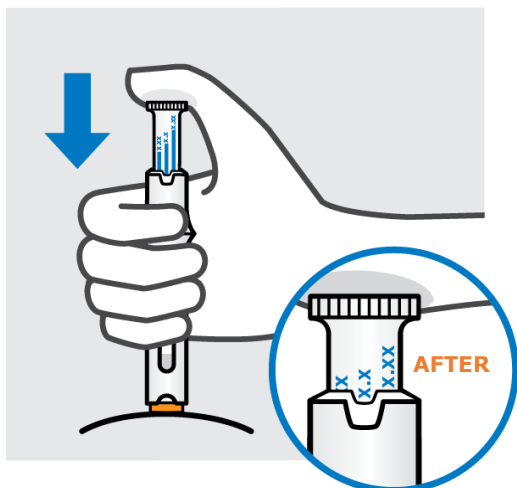
0.45 mL

**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

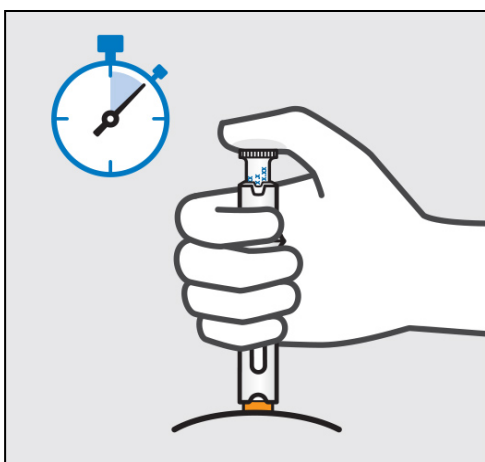
Keep pushing the pre-filled pen against the skin.

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.

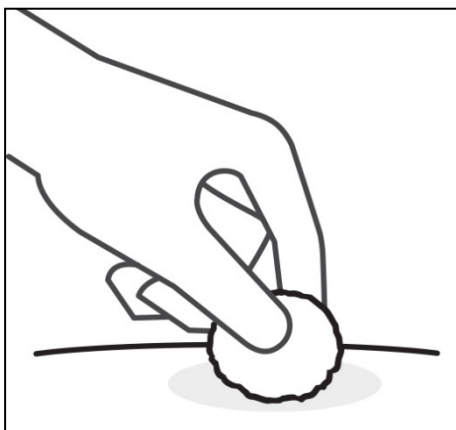
3. After your injection



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!

INSTRUCTIONS FOR USE

Simponi 50 mg solution for injection in 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 doctor, nurse or pharmacist to schedule a training session.

In these instructions:

1. Preparing for use of the pre-filled pen
2. Choosing and preparing the injection site
3. Injecting the medicine
4. After the injection

The diagram below (see figure 1) shows what the "SmartJect" pre-filled pen looks like.

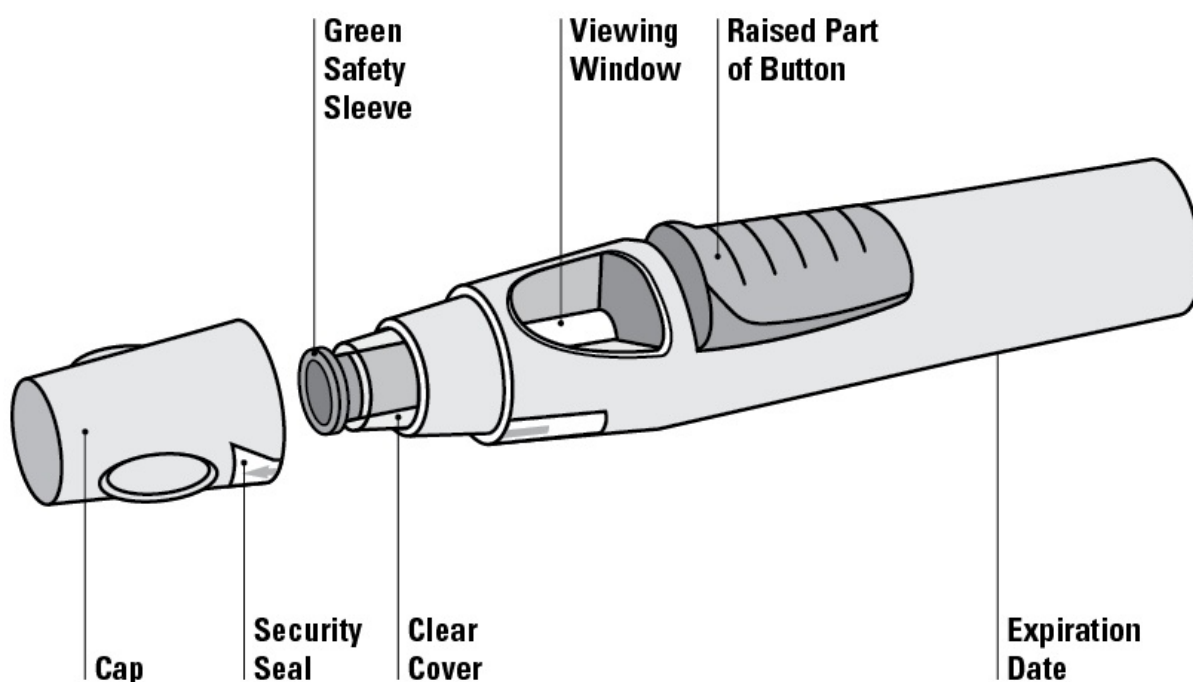


Figure 1

1. Preparing for use of the pre-filled pen

- Do not shake the pre-filled pen at any time.
- Do not remove the cap from the pre-filled pen until immediately before the injection.

- Do not put the cap of the pre-filled pen back on if removed to avoid bending the needle.

Check the number of pre-filled pens

Check the pre-filled pens to make sure

- the number of pre-filled pens and strength is correct
 - If your dose is 50 mg, you will get one 50 mg pre-filled pen
 - If your dose is 100 mg, you will get two 50 mg pre-filled pens and you will need to give yourself two injections. Choose two different sites for these injections (e.g. one injection in the right thigh and the other injection in the left thigh), and give the injections one right after the other.
 - If your dose is 200 mg, you will get four 50 mg pre-filled pens and you will need to give yourself four injections. Choose different sites for these injections and give the injections one right after the other.

Check expiry date

- Check the expiration date printed or written on the carton.
- Check the expiration date (as indicated as "EXP") on the pre-filled pen.
- Do not use the pre-filled pen if the expiration date has passed. The printed expiration date refers to the last day of the month. Please contact your doctor or pharmacist for assistance.

Check security seal

- Check the security seal around the cap of the pre-filled pen.
- Do not use the pre-filled pen if the seal is broken. Please contact your doctor or pharmacist.

Wait 30 minutes to allow pre-filled pen to reach room temperature

- To ensure proper injection, allow the pre-filled pen to sit at room temperature outside the box for 30 minutes out of the reach of children.
- Do not warm the pre-filled pen in any other way (for example, do not warm it in a microwave or in hot water).
- Do not remove the pre-filled pen's cap while allowing it to reach room temperature.

Get the rest of your equipment ready

- While you are waiting you can get the rest of your equipment ready, including an alcohol swab, a cotton ball or gauze and a sharps container.

Check the liquid in the pre-filled pen

- Look through the viewing window to make sure that the liquid in the pre-filled pen is clear to slightly opalescent (having a pearl-like shine) and colourless to light yellow.

The solution can be used if it contains a few small translucent or white particles of protein.

- You will also notice an air bubble, which is normal.
- Do not use the pre-filled pen if the liquid is the wrong colour, cloudy, or contains larger particles. If this happens, talk to your doctor or pharmacist.

2. Choosing and preparing the injection site (see figure 2)

- You can inject the medicine into the front of the middle thighs.
- You can use the stomach (abdomen) below the belly button, except for approximately the 5 cm area directly underneath the belly button.
- Do not inject into areas where the skin is tender, bruised, red, scaly, hard or has scars or stretch marks.
- If multiple injections are required for a single administration, the injections should be administered at different injection sites.

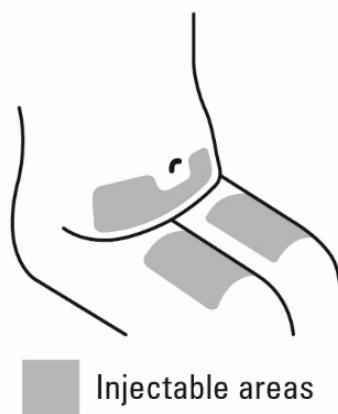


Figure 2

! **DO NOT** inject into the arm to avoid failure of the pre-filled pen and/or unintentional injury.

Wash hands and clean the injection site

- Wash your hands thoroughly with soap and warm water.
- Wipe the injection site with an alcohol swab.
- Allow the skin to dry before injecting. Do not fan or blow on the clean area.
- Do not touch this area again before giving the injection.

3. Injecting the medicine

- The cap should not be removed until you are ready to inject the medicine.
- The medicine should be injected within 5 minutes after the cap has been removed.

Remove the cap (figure 3)

- When you are ready to inject, twist the cap slightly to break the security seal.
- Pull the cap off and throw it away after your injection.
- Do not put the cap back on because it may damage the needle inside the pre-filled pen.
- Do not use the pre-filled pen if it is dropped without the cap in place. If this happens please contact your doctor or pharmacist.

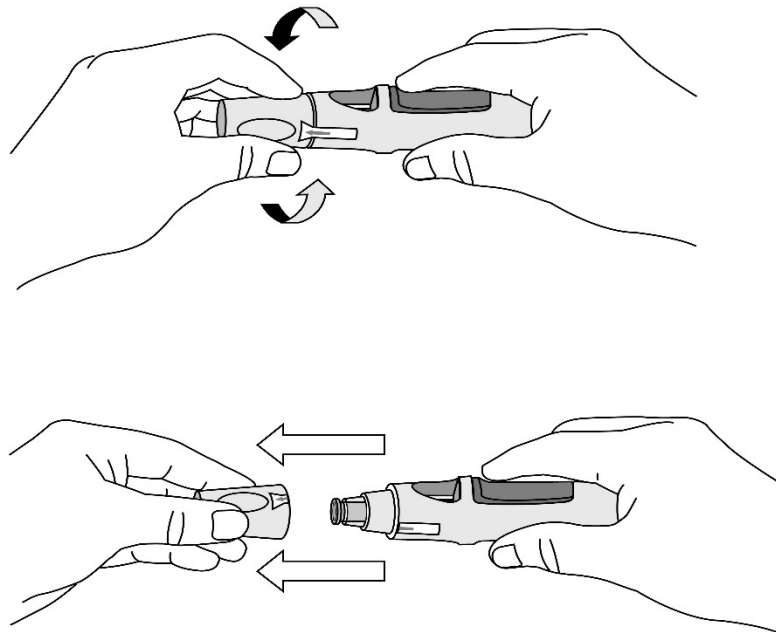


Figure 3

Push the pre-filled pen against the skin (see figures 4 and 5) without pinching the skin.

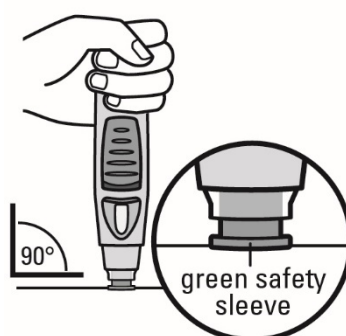


Figure 4

- Hold the pre-filled pen comfortably with one hand **above the blue button** .
- Make sure the green safety sleeve is stable and is as flat as possible against your skin. If the pre-filled pen is not stable during the injection, you risk bending the needle.
- **DO NOT** pinch the skin to avoid unintentional needlestick injury.
- **DO NOT** touch or press the blue button while positioning the pre-filled pen onto your skin.

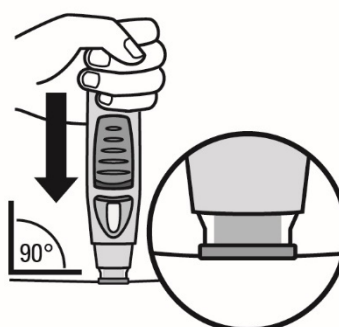


Figure 5

- Push the open end of the pre-filled pen against the skin at a 90-degree angle. Apply enough pressure to slide the green safety sleeve up and to maintain it inside the clear cover. Only the wider portion of the green safety sleeve remains outside of the clear cover.
- **DO NOT** press the blue button until after the safety sleeve slides into the clear cover. Pushing the blue button before the safety sleeve is depressed can lead to pen failure.
- Inject without pinching the skin.

Press button to inject (see figures 6 and 7)

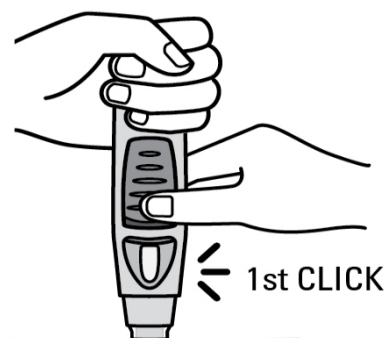


Figure 6

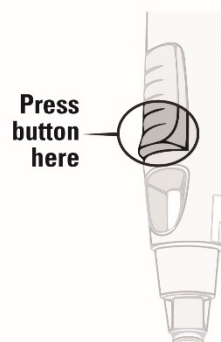


Figure 7

- Continue to push the pre-filled pen against your skin. **Use your other hand** to press the **raised part of the blue button** to start your injection. Do not press the button unless the pre-filled pen is **pressed 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.
- If the button seems hard to depress, don't press the button harder. Let go of the button, lift the pre-filled pen and start again. Ensure no pressure is on the button until the green safety sleeve is fully depressed against the skin, then press the raised part of the button.
- **You will hear a loud 'click' sound – don't be alarmed.** The first 'click' means 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 pre-filled pen away from your skin. If you pull the pre-filled pen away from your skin, you may not get your full dose of medicine.

Continue to hold until the second 'click' (see figure 8), it usually takes about 3 to 6 seconds, but may take up to 15 seconds for you to hear the second 'click' sound.

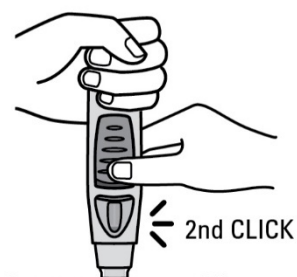


Figure 8

- **Continue to hold the pre-filled pen against your skin until you hear a second 'click' (indicating that the injection has finished and the needle has gone back into the pre-filled pen).**
- Lift the pre-filled pen from the injection site.

- Note: If you do not hear the second 'click', wait 15 seconds from the time you first press the button and then lift the autoinjector from the injection site.

4. After the injection

Use a cotton ball or gauze

- There may be a small amount of blood or liquid at the injection site. This is normal.
- You can press a cotton ball or gauze over the injection site for 10 seconds.
- You may cover the injection site with a small adhesive bandage, if necessary.
- Do not rub your skin.

Check the window – a yellow indicator confirms proper administration (see figure 9)

- The yellow indicator is connected to the plunger of the pre-filled pen. If the yellow indicator is not shown in the window, the plunger has not advanced adequately, and the injection has not occurred.
- The yellow indicator will fill about half of the viewing window. This is normal.
- Talk to your doctor or pharmacist if the yellow indicator is not visible in the window or if you suspect that you may not have received a complete dose. Do not administer a second dose without speaking to your doctor.

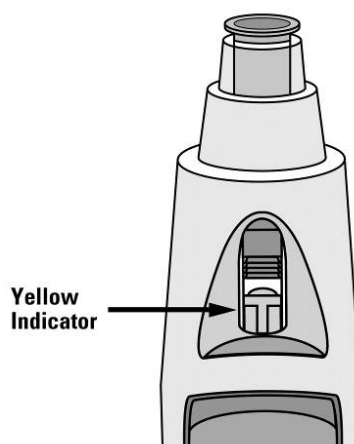


Figure 9

Throw the pre-filled pen away (see figure 10)

- Place your pen in a sharps container straight away. Make sure you dispose of the bin as instructed by your doctor or nurse when the container is full.

If you feel that something has gone wrong with the injection or if you are not sure, talk to your doctor or pharmacist.



Figure 10

INSTRUCTIONS FOR USE

Simponi 50 mg solution for injection in pre-filled syringe

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 doctor, nurse or pharmacist to schedule a training session.

In these instructions:

1. Preparing for use of the pre-filled syringe
2. Choosing and preparing the injection site
3. Injecting the medicine
4. After the injection

The diagram below (see figure 1) shows what the pre-filled syringe looks like.

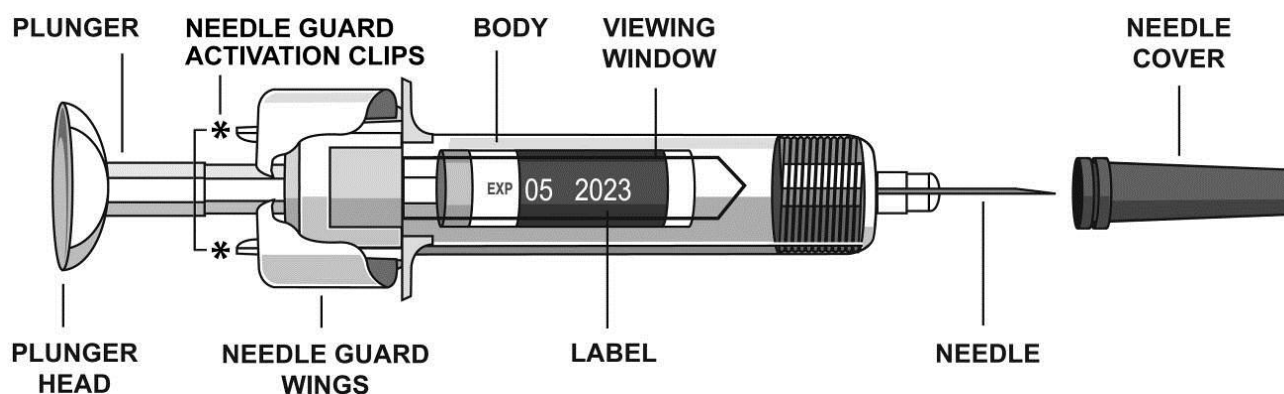


Figure 1

1. Preparing for use of the pre-filled syringe

Hold the pre-filled syringe by the body of the pre-filled syringe

- Do not hold by the plunger head, plunger, needle guard wings, or needle cover.
- Do not pull back on the plunger at any time.
- 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.
- Do not touch the needle guard activation clips (as indicated by asterisks * in figure 1) to prevent prematurely covering the needle with the needle guard.

Check the number of pre-filled syringes

Check the pre-filled syringes to make sure

- the number of pre-filled syringes and strength is correct
 - If your dose is 50 mg, you will get one 50 mg pre-filled syringe
 - If your dose is 100 mg, you will get two 50 mg pre-filled syringes and you will need to give yourself two injections. Choose two different sites for these injections (e.g. one injection in the right thigh and the other injection in the left thigh), and give the injections one right after the other.
 - If your dose is 200 mg, you will get four 50 mg pre-filled syringes and you will need to give yourself four injections. Choose different sites for these injections and give the injections one right after the other.

Check expiry date (see figure 2)

- Check the expiration date printed or written on the carton.
- Check the expiration 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 expiration date through the viewing window, hold the pre-filled syringe by its body and rotate the needle cover to line up the expiration date to the viewing window.

Do not use the pre-filled syringe if the expiration date has passed. The printed expiration date refers to the last day of the month. Please contact your doctor or pharmacist for assistance.

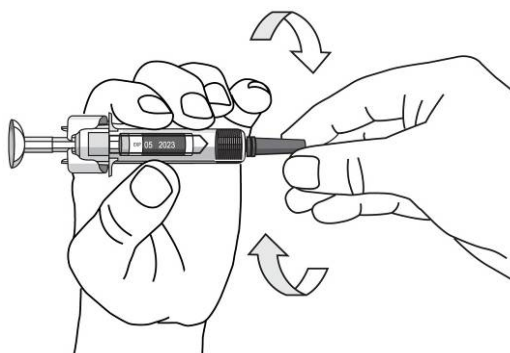


Figure 2

Wait 30 minutes to allow pre-filled syringe to reach room temperature

- To ensure proper injection, allow the pre-filled syringe to sit at room temperature outside the box for 30 minutes, out of the reach of children.

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 remove the pre-filled syringe's needle cover while allowing it to reach room temperature.

Get the rest of your equipment ready

While you are waiting you can get the rest of your equipment ready, including an alcohol swab, a cotton ball or gauze and a sharps container.

Check the liquid in the pre-filled syringe

- Hold the pre-filled syringe by its body with the covered needle pointing downward.
- Look at the liquid through the viewing window of the pre-filled syringe and make sure that it is clear to slightly opalescent (having a pearl-like shine) and colourless to light yellow. The solution can be used if it contains a few small translucent or white particles of protein.
- If you cannot see the liquid through the viewing window, hold the pre-filled syringe by its body and rotate the needle cover to line up the liquid to the viewing window (see figure 2).

Do not use the pre-filled syringe if the liquid is the wrong colour, cloudy, or contains larger particles. If this happens, talk to your doctor or pharmacist.

2. Choosing and preparing the injection site (see figure 3)

- You usually inject the medicine into the front of the middle thighs.
- You can also use the lower stomach (abdomen) below the belly button, except for approximately the 5 cm area directly underneath the belly button.
- Do not inject into areas where the skin is tender, bruised, red, scaly, hard or has scars or stretch marks.
- If multiple injections are required for a single administration, the injections should be administered at different sites on the body.

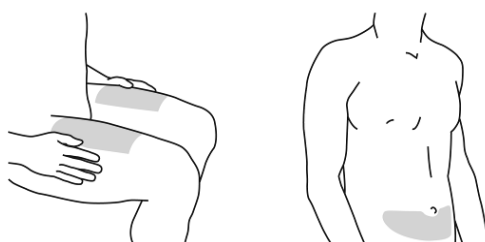


Figure 3

Injection site selection for caregivers (see figure 4)

- If a caregiver is giving you the injection, they can also use the outer area of the upper arms.
- Again, all sites mentioned can be used regardless of your body type or size.

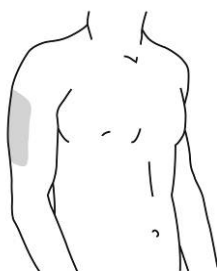


Figure 4

Preparing injection site

- Wash your hands thoroughly with soap and warm water.
- Wipe the injection site with an alcohol swab.
- Allow the skin to dry before injecting. Do not fan or blow on the clean area.

Do not touch this area again before giving the injection.

3. Injecting the medicine

The needle cover should not be removed until you are ready to inject the medicine. The medicine should be injected within 5 minutes after the needle cover has been removed.

Do not touch the plunger during needle cover removal.

Remove the needle cover (see figure 5)

- When you are ready to inject, hold the body of the pre-filled syringe with one hand.
- Pull the needle cover straight off and throw it away after your injection. Do not touch the plunger while you do this.
- You may notice an air bubble in the pre-filled syringe or a drop of liquid at the end of the needle. These are both normal and do not need to be removed.
- Inject the dose promptly after removing the needle cover.

Do not touch the needle or allow it to touch any surface.

Do not use the pre-filled syringe if it is dropped without the needle cover in place. If this happens, please contact your doctor or pharmacist.

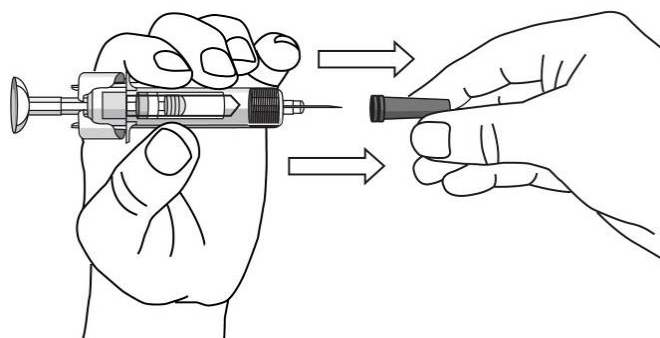


Figure 5

Position the pre-filled syringe to inject

- Hold the body of the pre-filled syringe with one hand between the middle and index fingers and place the thumb on top of the plunger head and use the other hand to gently pinch the area of skin that you previously cleaned. Hold firmly.

Do not pull back on the plunger at any time.

Inject the medicine

- Place the needle at approximately a 45-degree angle to the pinched skin. In a single and swift motion, insert the needle through the skin as far as it will go (see figure 6).

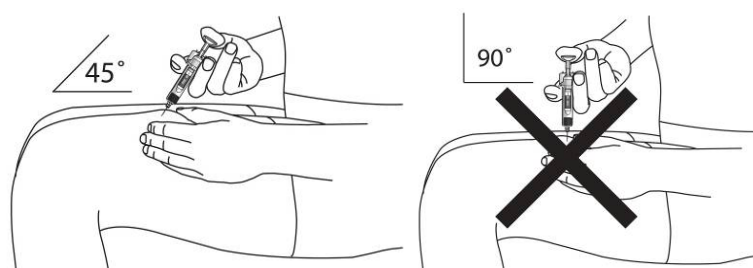


Figure 6

- Inject all of the medicine by pushing in the plunger until the plunger head is completely between the needle guard wings (see figure 7).

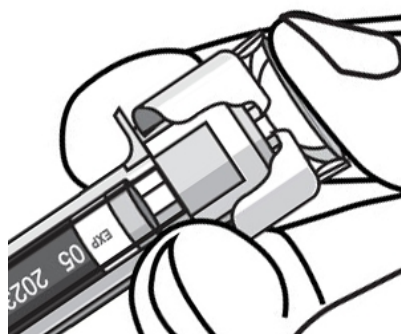


Figure 7

- When the plunger is pushed as far as it will go, continue to keep the pressure on the plunger head, take out the needle and let go of the skin (see figure 8).

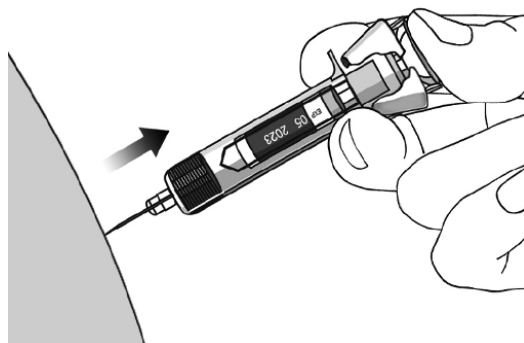


Figure 8

- Slowly take your thumb off the plunger head to allow the empty pre-filled syringe to move up until the entire needle is covered by the needle guard, as shown by the figure 9:

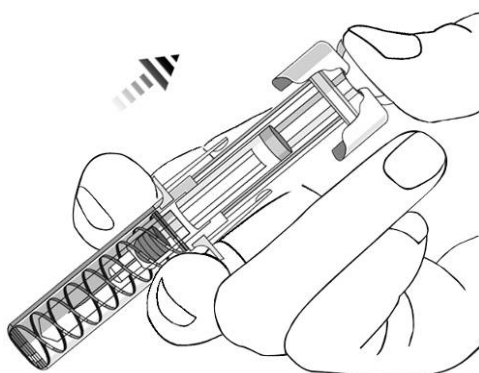


Figure 9

4. After the injection

Use a cotton ball or gauze

- There may be a small amount of blood or liquid at the injection site. This is normal.
- You can press a cotton ball or gauze over the injection site and hold for 10 seconds.
- You may cover the injection site with a small adhesive bandage, if necessary.

Do not rub your skin.

Throw the pre-filled syringe away (see figure 10)

- Place your pre-filled syringe in a sharps container straight away. Make sure you dispose of the bin as instructed by your doctor or nurse.

Do not attempt to recap the needle.

Do not ever re-use a pre-filled syringe, for your safety and health and for the safety of others.

If you feel that something has gone wrong with the injection or if you are not sure, talk to your doctor or pharmacist.

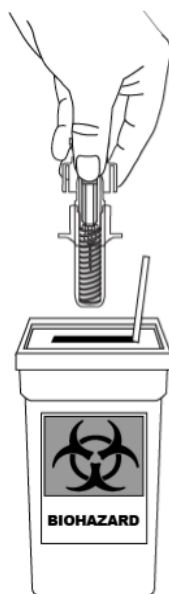


Figure 10

INSTRUCTIONS FOR USE

Simponi 100 mg solution for injection in 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 doctor, nurse or pharmacist to schedule a training session.

In these instructions:

1. Preparing for use of the pre-filled pen
2. Choosing and preparing the injection site
3. Injecting the medicine
4. After the injection

The diagram below (see figure 1) shows what the “SmartJect” pre-filled pen looks like.

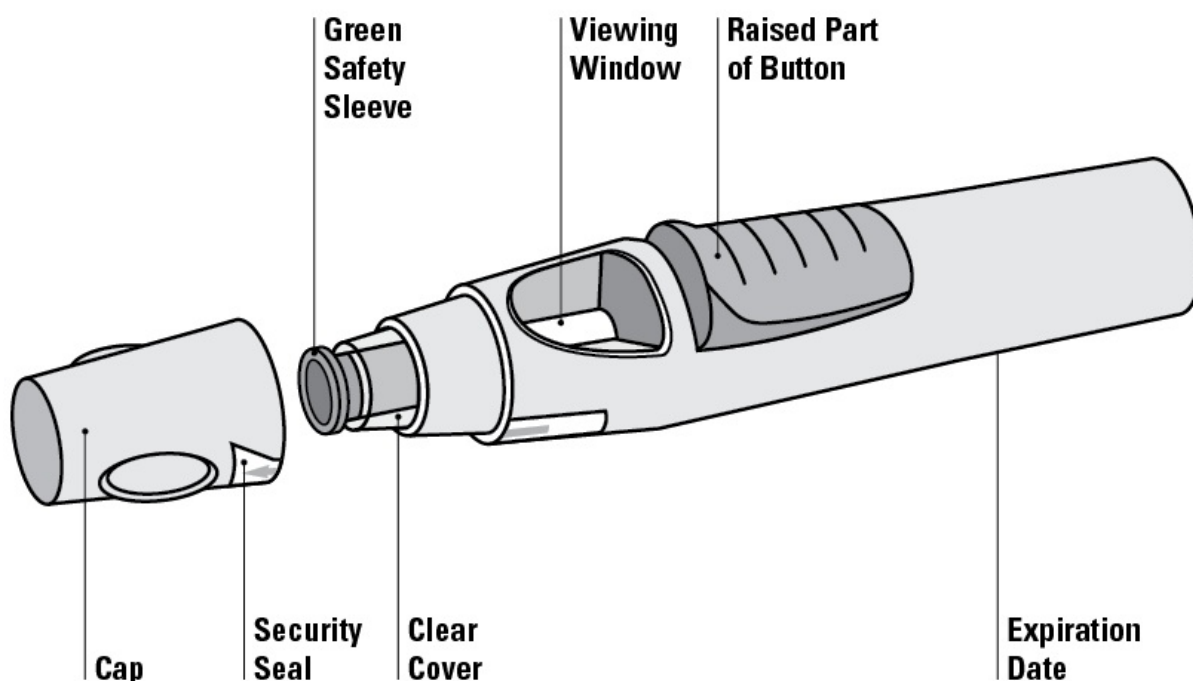


Figure 1

1. Preparing for use of the pre-filled pen

- Do not shake the pre-filled pen at any time.
- Do not remove the cap from the pre-filled pen until immediately before the injection.

- Do not put the cap of the pre-filled pen back on if removed to avoid bending the needle.

Check the number of pre-filled pens

Check the pre-filled pens to make sure

- the number of pre-filled pens and strength is correct
 - If your dose is 100 mg, you will get one 100 mg pre-filled pen
 - If your dose is 200 mg, you will get two 100 mg pre-filled pens and you will need to give yourself two injections. Choose different sites for these injections and give the injections one right after the other.

Check expiry date

- Check the expiration date printed or written on the carton.
- Check the expiration date (as indicated as "EXP") on the pre-filled pen.
- Do not use the pre-filled pen if the expiration date has passed. The printed expiration date refers to the last day of the month. Please contact your doctor or pharmacist for assistance.

Check security seal

- Check the security seal around the cap of the pre-filled pen.
- Do not use the pre-filled pen if the seal is broken. Please contact your doctor or pharmacist.

Wait 30 minutes to allow pre-filled pen to reach room temperature

- To ensure proper injection, allow the pre-filled pen to sit at room temperature outside the box for 30 minutes out of the reach of children.
- Do not warm the pre-filled pen in any other way (for example, do not warm it in a microwave or in hot water).
- Do not remove the pre-filled pen's cap while allowing it to reach room temperature.

Get the rest of your equipment ready

- While you are waiting you can get the rest of your equipment ready, including an alcohol swab, a cotton ball or gauze and a sharps container.

Check the liquid in the pre-filled pen

- Look through the viewing window to make sure that the liquid in the pre-filled pen is clear to slightly opalescent (having a pearl-like shine) and colourless to light yellow. The solution can be used if it contains a few small translucent or white particles of protein.

- You will also notice an air bubble, which is normal.
- Do not use the pre-filled pen if the liquid is the wrong colour, cloudy, or contains larger particles. If this happens, talk to your doctor or pharmacist.

2. Choosing and preparing the injection site (see figure 2)

- You can inject the medicine into the front of the middle thighs.
- You can use the stomach (abdomen) below the belly button, except for approximately the 5 cm area directly underneath the belly button.
- Do not inject into areas where the skin is tender, bruised, red, scaly, hard or has scars or stretch marks.
- If multiple injections are required for a single administration, the injections should be administered at different injection sites.

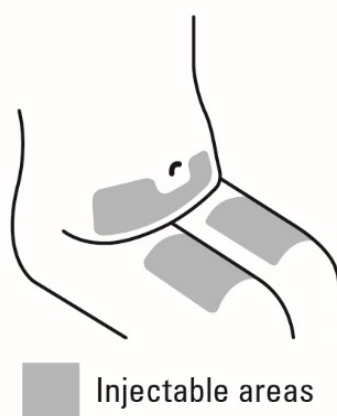


Figure 2

⚠ DO NOT inject into the arm to avoid failure of the pre-filled pen and/or unintentional injury.

Wash hands and clean injection site

- Wash your hands thoroughly with soap and warm water.
- Wipe the injection site with an alcohol swab.
- Allow the skin to dry before injecting. Do not fan or blow on the clean area.
- Do not touch this area again before giving the injection.

3. Injecting the medicine

- The cap should not be removed until you are ready to inject the medicine.
- The medicine should be injected within 5 minutes after the cap has been removed.

Remove the cap (figure 3)

- When you are ready to inject, twist the cap slightly to break the security seal.
- Pull the cap off and throw it away after your injection.
- Do not put the cap back on because it may damage the needle inside the pre-filled pen.
- Do not use the pre-filled pen if it is dropped without the cap in place. If this happens please contact your doctor or pharmacist.

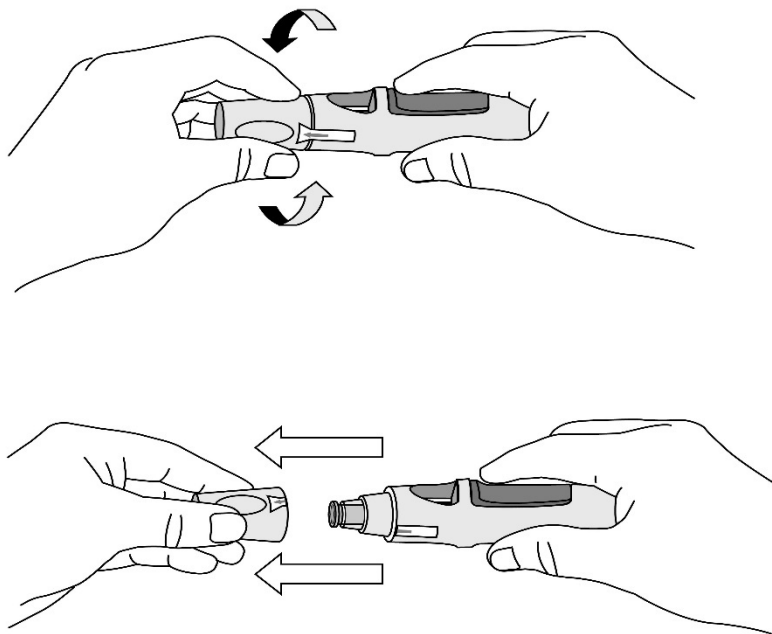


Figure 3

Push the pre-filled pen against the skin (see figures 4 and 5) without pinching the skin.

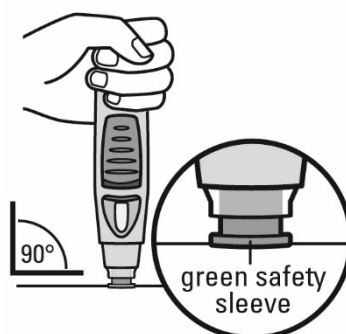


Figure 4

- Hold the pre-filled pen comfortably with one hand **above the blue button**.
- Make sure the green safety sleeve is stable and is as flat as possible against your skin. If the pre-filled pen is not stable during the injection, you risk bending the needle.

- DO NOT pinch the skin to avoid unintentional needlestick injury.
- **DO NOT** touch or press the blue button while positioning the pre-filled pen onto your skin.

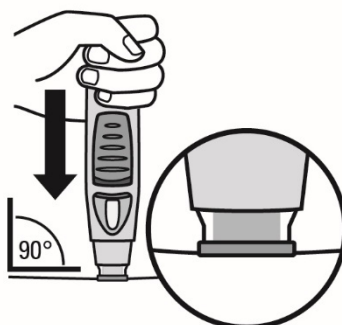


Figure 5

- Push the open end of the pre-filled pen against the skin at a 90-degree angle. Apply enough pressure to slide the green safety sleeve up and to maintain it inside the clear cover. Only the wider portion of the green safety sleeve remains outside of the clear cover.
- DO NOT press the blue button until after the safety sleeve slides into the clear cover. Pushing the blue button before the safety sleeve is depressed can lead to pen failure.
- Inject without pinching the skin.

Press button to inject (see figures 6 and 7)

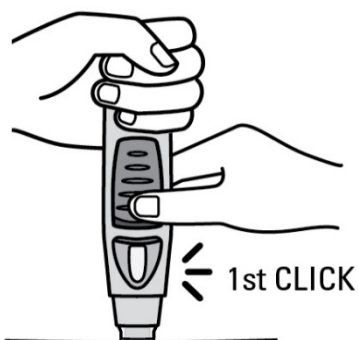


Figure 6

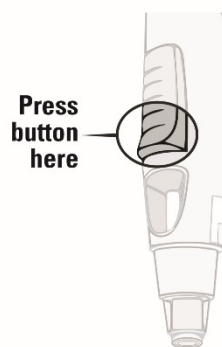


Figure 7

- Continue to push the pre-filled pen against your skin. **Use your other hand** to press the **raised part of the blue button** to start your injection. Do not press the button unless the pre-filled pen is **pressed 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.
- If the button seems hard to depress, don't press the button harder. Let go of the button, lift the pre-filled pen and start again. Ensure no pressure is on the button until the green safety sleeve is fully depressed against the skin, then press the raised part of the button.

- **You will hear a loud 'click' sound – don't be alarmed.** The first 'click' means 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 pre-filled pen away from your skin. If you pull the pre-filled pen away from your skin, you may not get your full dose of medicine.

Continue to hold until the second 'click' (see figure 8), it usually takes about 3 to 6 seconds, but may take up to 15 seconds for you to hear the second 'click' sound.

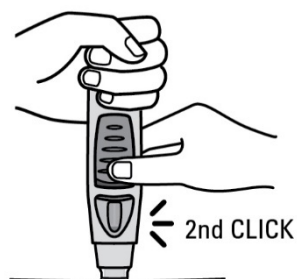


Figure 8

- **Continue to hold the pre-filled pen against your skin until you hear a second 'click' (indicating that the injection has finished and the needle has gone back into the pre-filled pen).**
- Lift the pre-filled pen from the injection site.
- Note: If you do not hear the second 'click', wait 15 seconds from the time you first press the button and then lift the autoinjector from the injection site.

4. After the injection

Use a cotton ball or gauze

- There may be a small amount of blood or liquid at the injection site. This is normal.
- You can press a cotton ball or gauze over the injection site for 10 seconds.
- You may cover the injection site with a small adhesive bandage, if necessary.
- Do not rub your skin.

Check the window – a yellow indicator confirms proper administration (see figure 9)

- The yellow indicator is connected to the plunger of the pre-filled pen. If the yellow indicator is not shown in the window, the plunger has not advanced adequately, and the injection has not occurred.
- The yellow indicator will fill about half of the viewing window. This is normal.

- Talk to your doctor or pharmacist if the yellow indicator is not visible in the window or if you suspect that you may not have received a complete dose. Do not administer a second dose without speaking to your doctor.

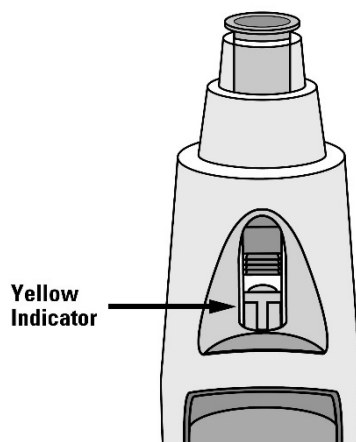


Figure 9

Throw the pre-filled pen away (see figure 10)

- Place your pen in a sharps container straight away. Make sure you dispose of the bin as instructed by your doctor or nurse when the container is full.

If you feel that something has gone wrong with the injection or if you are not sure, talk to your doctor or pharmacist.



Figure 10

INSTRUCTIONS FOR USE

Simponi 100 mg solution for injection in pre-filled syringe

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 doctor, nurse or pharmacist to schedule a training session.

In these instructions:

1. Preparing for use of the pre-filled syringe
2. Choosing and preparing the injection site
3. Injecting the medicine
4. After the injection

The diagram below (see figure 1) shows what the pre-filled syringe looks like.

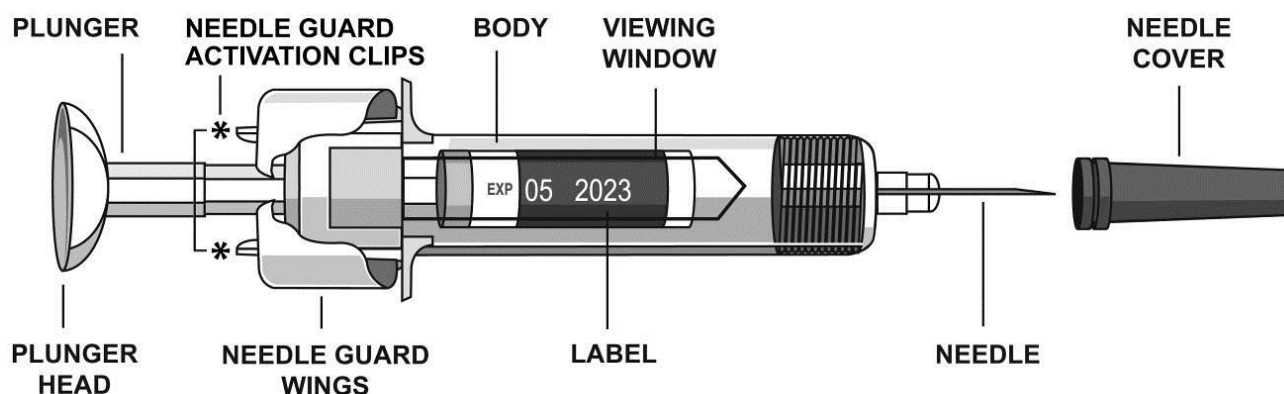


Figure 1

1. Preparing for use of the pre-filled syringe

Hold the pre-filled syringe by the body of the pre-filled syringe

- Do not hold by the plunger head, plunger, needle guard wings, or needle cover.
- Do not pull back on the plunger at any time.
- 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.
- Do not touch the needle guard activation clips (as indicated by asterisks * in figure 1) to prevent prematurely covering the needle with the needle guard.

Check the number of pre-filled syringes

Check the pre-filled syringes to make sure

- the number of pre-filled syringes and strength is correct
 - If your dose is 100 mg, you will get one 100 mg pre-filled syringe
 - If your dose is 200 mg, you will get two 100 mg pre-filled syringes and you will need to give yourself two injections. Choose different sites for these injections and give the injections one right after the other.

Check expiry date (see figure 2)

- Check the expiration date printed or written on the carton.
- Check the expiration 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 expiration date through the viewing window, hold the pre-filled syringe by its body and rotate the needle cover to line up the expiration date to the viewing window.

Do not use the pre-filled syringe if the expiration date has passed. The printed expiration date refers to the last day of the month. Please contact your doctor or pharmacist for assistance.

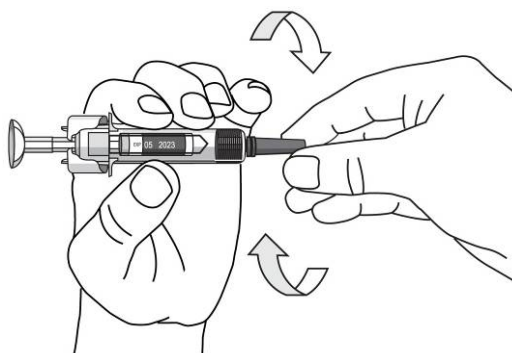


Figure 2

Wait 30 minutes to allow pre-filled syringe to reach room temperature

- To ensure proper injection, allow the pre-filled syringe to sit at room temperature outside the box for 30 minutes, out of the reach of children.

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 remove the pre-filled syringe's needle cover while allowing it to reach room temperature.

Get the rest of your equipment ready

While you are waiting you can get the rest of your equipment ready, including an alcohol swab, a cotton ball or gauze and a sharps container.

Check the liquid in the pre-filled syringe

- Hold the pre-filled syringe by its body with the covered needle pointing downward.
- Look at the liquid through the viewing window of the pre-filled syringe and make sure that it is clear to slightly opalescent (having a pearl-like shine) and colourless to light yellow. The solution can be used if it contains a few small translucent or white particles of protein.
- If you cannot see the liquid through the viewing window, hold the pre-filled syringe by its body and rotate the needle cover to line up the liquid to the viewing window (see figure 2).

Do not use the pre-filled syringe if the liquid is the wrong colour, cloudy, or contains larger particles. If this happens, talk to your doctor or pharmacist.

2. Choosing and preparing the injection site (see figure 3)

- You usually inject the medicine into the front of the middle thighs.
- You can also use the lower stomach (abdomen) below the belly button, except for approximately the 5 cm area directly underneath the belly button.
- Do not inject into areas where the skin is tender, bruised, red, scaly, hard or has scars or stretch marks.
- If multiple injections are required for a single administration, the injections should be administered at different sites on the body.

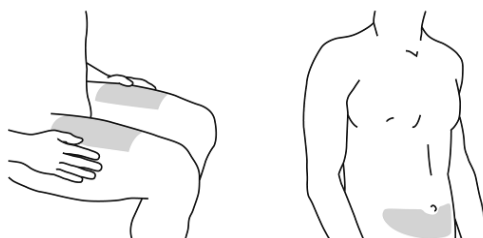


Figure 3

Injection site selection for caregivers (see figure 4)

- If a caregiver is giving you the injection, they can also use the outer area of the upper arms.
- Again, all sites mentioned can be used regardless of your body type or size.

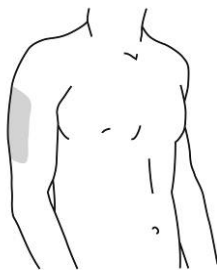


Figure 4

Preparing injection site

- Wash your hands thoroughly with soap and warm water.
- Wipe the injection site with an alcohol swab.
- Allow the skin to dry before injecting. Do not fan or blow on the clean area.

Do not touch this area again before giving the injection.

3. Injecting the medicine

The needle cover should not be removed until you are ready to inject the medicine. The medicine should be injected within 5 minutes after the needle cover has been removed.

Do not touch the plunger during needle cover removal.

Remove the needle cover (see figure 5)

- When you are ready to inject, hold the body of the pre-filled syringe with one hand.
- Pull the needle cover straight off and throw it away after your injection. Do not touch the plunger while you do this.
- You may notice an air bubble in the pre-filled syringe or a drop of liquid at the end of the needle. These are both normal and do not need to be removed.
- Inject the dose promptly after removing the needle cover.

Do not touch the needle or allow it to touch any surface.

Do not use the pre-filled syringe if it is dropped without the needle cover in place. If this happens, please contact your doctor or pharmacist.

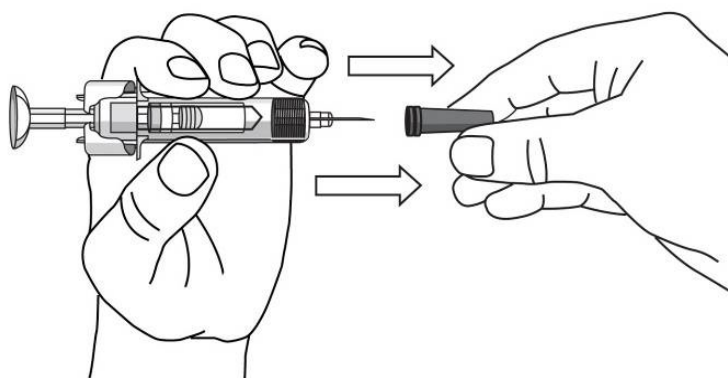


Figure 5

Position the pre-filled syringe to inject

- Hold the body of the pre-filled syringe with one hand between the middle and index fingers and place the thumb on top of the plunger head and use the other hand to gently pinch the area of skin that you previously cleaned. Hold firmly.

Do not pull back on the plunger at any time.

Inject the medicine

- Place the needle at approximately a 45-degree angle to the pinched skin. In a single and swift motion, insert the needle through the skin as far as it will go (see figure 6).

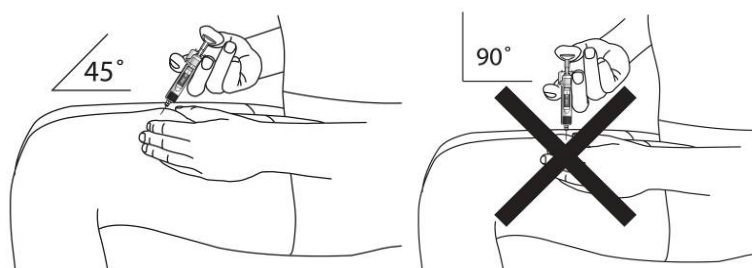


Figure 6

- Inject all of the medicine by pushing in the plunger until the plunger head is completely between the needle guard wings (see figure 7).



Figure 7

- When the plunger is pushed as far as it will go, continue to keep the pressure on the plunger head, take out the needle and let go of the skin (see figure 8).

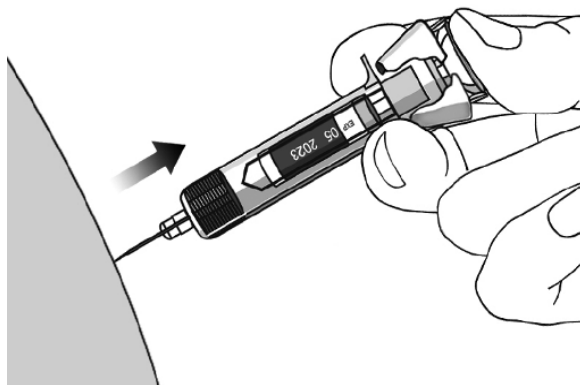


Figure 8

- Slowly take your thumb off the plunger head to allow the empty pre-filled syringe to move up until the entire needle is covered by the needle guard, as shown by the figure 9:

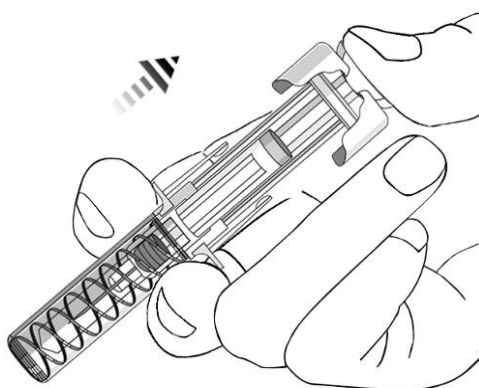


Figure 9

4. After the injection

Use a cotton ball or gauze

- There may be a small amount of blood or liquid at the injection site. This is normal.
- You can press a cotton ball or gauze over the injection site and hold for 10 seconds.
- You may cover the injection site with a small adhesive bandage, if necessary.

Do not rub your skin.

Throw the pre-filled syringe away (see figure 10)

- Place your pre-filled syringe in a sharps container straight away. Make sure you dispose of the bin as instructed by your doctor or nurse.

Do not attempt to recap the needle.

Do not ever re-use a pre-filled syringe, for your safety and health and for the safety of others.

If you feel that something has gone wrong with the injection or if you are not sure, talk to your doctor or pharmacist.

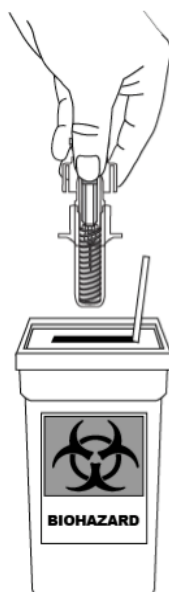


Figure 10

Date of revision of the text

EU SmPC version 22-Jun-2023

MARKETING AUTHORISATION NUMBER(S) AND DATE OF AUTHORIZATION

Product Name	License number	Manufactured by	Date of Authorization
SIMPONI SOLUTION FOR INJECTION	1C 1/57 (NB)	Baxter Pharmaceutical Solution LLC, Indiana, USA	24-Jan-2014

Imported by

Janssen-Cilag Ltd., Bangkok, Thailand

To report Suspected Adverse Reactions, please contact us at aepqjacth@its.jnj.com

For any product information, please contact us at medinfosea@its.jnj.com

Please see full prescribing information at <https://ndi.fda.moph.go.th>