

## **Patient Medication Information - Subcutaneous**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

Pr **SAPHNELO®**

#### **Anifrolumab injection, subcutaneous**

This Patient Medication Information is written for the person who will be taking **SAPHNELO**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **SAPHNELO**, talk to a healthcare professional.

#### **What SAPHNELO is used for:**

SAPHNELO is used for the treatment of:

- active lupus (systemic lupus erythematosus, SLE) in adults whose disease is not well controlled by other standard therapies (oral corticosteroids and/or immunosuppressants and/or antimalarials) they are also receiving. You will be given SAPHNELO as well as your standard therapy for lupus.

Lupus is a disease in which the immune system (the system that fights infection) attacks your own cells and tissues, causing inflammation and organ damage. It can affect almost any organ in the body, including skin, joints, kidneys, brain and other organs, and can cause pain, rashes, fatigue, swelling in joints, and fevers.

#### **How SAPHNELO works:**

SAPHNELO contains anifrolumab, a monoclonal antibody (a type of specialized protein) that blocks the action of a group of proteins called Type I Interferons (IFN). Type I Interferons are found at high levels in people with lupus and blocking them can reduce the inflammation in your body that causes the signs and symptoms of lupus.

SAPHNELO may help to reduce your lupus disease activity and the number of lupus flares you are experiencing. If you are taking medicines called 'oral corticosteroids', using SAPHNELO may also allow your healthcare professional to reduce your daily dose of the oral corticosteroids that are needed to help control your lupus.

#### **The ingredients in SAPHNELO are:**

Medicinal ingredient: anifrolumab

Non-medicinal ingredients: L-Histidine, L-Histidine hydrochloride monohydrate, L-Lysine hydrochloride, Polysorbate 80, Trehalose dihydrate, Water for injection.

#### **SAPHNELO comes in the following dosage form:**

Solution for injection: 120 mg / 0.8 mL (150 mg / mL) in autoinjector.

There are 4 autoinjectors in each pack.

**Do not use SAPHNELO if:**

- you are allergic to anifrolumab or to any ingredients in SAPHNELO. If you are not sure, talk to your healthcare professional before you are given SAPHNELO.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take SAPHNELO. Talk about any health conditions or problems you may have, including if you:**

- think you have had an allergic reaction to this medicine at any time.
- get an infection or have symptoms of an infection.
- have a long-term (chronic) infection or if you have an infection that keeps coming back.
- have, or have had, cancer.
- have recently received or plan to receive an immunization (vaccine). You should not be given certain types of vaccines while using SAPHNELO.

**Other warnings you should know about:****Infections**

- You may be at more risk of getting an infection when you are being treated with SAPHNELO, including infection of the airways and shingles.
- Signs of infections may include fever or flu-like symptoms, muscle aches, cough, shortness of breath, burning when you urinate or urinating more often than usual, diarrhea or stomach pain, shingles (a red skin rash that can cause pain and burning). Tell your healthcare professional as soon as possible if you notice any signs indicating a possible infection.

**Pregnancy**

- Before you start treatment with SAPHNELO, tell your healthcare professional if you are pregnant or think you may be pregnant. Your healthcare professional will decide if you can be given SAPHNELO.
- Talk to your healthcare professional if you plan to become pregnant while on SAPHNELO. It is not known if SAPHNELO can harm your unborn baby.
- If you become pregnant while being treated with SAPHNELO, tell your healthcare professional. They will discuss with you whether you should stop treatment with SAPHNELO.

**Breastfeeding**

- Before you start treatment with SAPHNELO, tell your healthcare professional if you are breastfeeding. It is not known whether SAPHNELO is passed into breast milk. Your healthcare professional will discuss with you whether you should stop treatment with SAPHNELO while you are breastfeeding, or if you should stop breastfeeding.

**Children and adolescents**

- SAPHNELO should not be used in children and adolescents below 18 years of age.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.****The following may interact with SAPHNELO:**

- certain types of vaccines. If you are not sure, talk to your healthcare professional before and during the use of SAPHNELO.

**How to take SAPHNELO:**

- Always use this medicine exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- Your healthcare professional will decide if you can inject SAPHNELO yourself or if your caregiver can do that for you. Before you use SAPHNELO, your healthcare professional should show you or your caregiver how to use SAPHNELO autoinjector in the right way.
- Inject SAPHNELO once per week, preferably on the same day each week. Set a reminder on a calendar to remind yourself of your weekly dose.
- Read the Instructions for Use before injecting SAPHNELO and each time you get a refill. There may be new information.
- Your healthcare professional will decide if you need to stop being given SAPHNELO. If you have any further questions on the use of this medicine, ask your healthcare professional.

### Usual dose:

The recommended dose is 120 mg once weekly, given as an injection under the skin (subcutaneous).

### Overdose:

If you think you, or a person you are caring for, have taken too much SAPHNELO, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

### Missed dose:

If you forget to use SAPHNELO, inject a dose as soon as you remember. Then, continue once weekly dosing based on the new day SAPHNELO was injected or on your regularly scheduled day as long as there are at least 3-days between the doses. If you are not sure when to inject SAPHNELO, call your healthcare professional.

### Possible side effects from using SAPHNELO:

These are not all the possible side effects you may have when taking SAPHNELO. If you experience any side effects not listed here, tell your healthcare professional.

- Upper respiratory infections (including nose or throat infections, sore throat and cold)
- Chest infection (bronchitis)
- Respiratory infections
- Joint pain

### Serious side effects and what to do about them

| Frequency/Side Effect/Symptom | Talk to your healthcare professional |              | Stop taking this drug and get immediate medical help |
|-------------------------------|--------------------------------------|--------------|------------------------------------------------------|
|                               | Only if severe                       | In all cases |                                                      |
| Common                        |                                      |              |                                                      |

| Frequency/Side Effect/Symptom                                                                                                                                                                                                                                 | Talk to your healthcare professional |              | Stop taking this drug and get immediate medical help |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------|------------------------------------------------------|
|                                                                                                                                                                                                                                                               | Only if severe                       | In all cases |                                                      |
| <b>Hypersensitivity</b> (allergic reactions) <b>or a reaction to the infusion/injection:</b> <ul style="list-style-type: none"> <li>wheezing</li> <li>itching</li> <li>rash</li> <li>hives</li> <li>nausea</li> <li>headache</li> <li>dizziness</li> </ul>    |                                      | ✓            |                                                      |
| <b>Herpes zoster</b> (shingles)                                                                                                                                                                                                                               |                                      | ✓            |                                                      |
| <b>Uncommon</b>                                                                                                                                                                                                                                               |                                      |              |                                                      |
| <b>Anaphylaxis</b> (serious allergic reaction): <ul style="list-style-type: none"> <li>swelling of your face, tongue, or mouth</li> <li>breathing difficulties</li> <li>fainting, dizziness, feeling lightheaded (due to a drop in blood pressure)</li> </ul> |                                      |              | ✓                                                    |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting ([canada.ca/drug-device-reporting](http://canada.ca/drug-device-reporting)) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

- Store at 2 to 8°C (in a refrigerator).
- Do not freeze or shake or expose to heat.
- Store in the original package in order to protect from light.
- If needed, SAPHNELO autoinjector may be stored at room temperature (20 to 25°C) for a maximum of 7 days protected from light. Once SAPHNELO autoinjector has reached room temperature, do not return to the refrigerator. Discard if not used within 7 days at room temperature storage.

- Keep out of reach and sight of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

**If you want more information about SAPHNELO:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [www.astrazeneca.ca](http://www.astrazeneca.ca); or by calling 1-800-668-6000.
- This Patient Medication Information is current at the time of printing. The most up-to-date version can be found at [www.astrazeneca.ca](http://www.astrazeneca.ca).

This leaflet was prepared by AstraZeneca Canada Inc., Mississauga, Ontario L4Y 1M4.

Date of Authorization: 2026-03-23

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## Instructions for Use – Autoinjector

Pr **SAPHNELO®**

### Anifrolumab injection

#### Solution for Subcutaneous Injection in a Single-use Autoinjector

This Instructions for Use contains information on how to inject using SAPHNELO autoinjector.

**Read this Instructions for Use before you start using SAPHNELO autoinjector and each time you get a refill. There may be new information.** This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Your healthcare provider should show you or your caregiver how to use SAPHNELO autoinjector the right way. If you or your caregiver have any questions, talk to your healthcare provider. SAPHNELO autoinjector is for use under the skin (subcutaneous) only.

### Important storage information and warnings

#### Storage:

- **Store SAPHNELO autoinjector in a refrigerator between 2 to 8°C in the original carton to protect from light.** If needed, SAPHNELO autoinjector may be stored at room temperature between 20 to 25°C for a maximum of 7 days **protected from light**.
- Once SAPHNELO autoinjector has reached room temperature, **do not** return to the refrigerator. Discard if not used within 7 days at room temperature storage.
- Each SAPHNELO autoinjector contains 1 dose for one time use only. **Do not** share SAPHNELO autoinjector with other people.
- **Keep SAPHNELO autoinjector and all medicines out of the sight and reach of children.**

#### Important warnings:

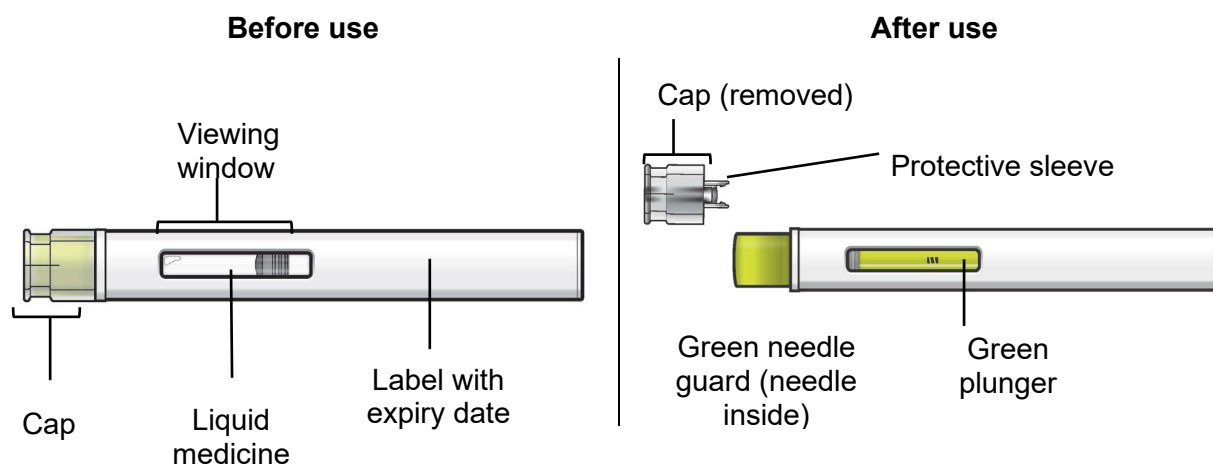
- **Do not** use SAPHNELO autoinjector if it has:
  - been frozen or exposed to heat.
  - been dropped, damaged, or appears to be tampered with.
- **Do not** shake SAPHNELO autoinjector.

If any of the above happens, throw away SAPHNELO autoinjector in a puncture-resistant (sharps) disposal container and use a new SAPHNELO autoinjector.

- Each SAPHNELO autoinjector contains 1 dose for one time use only. **Do not** share SAPHNELO autoinjector with other people.
- Inject SAPHNELO once per week, preferably on the same day each week. Set a reminder on a calendar to remind yourself of your weekly dose.

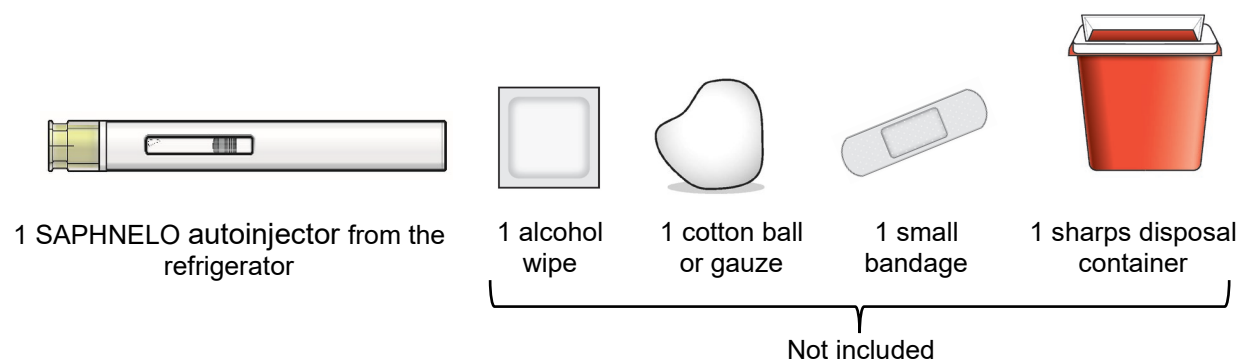
## SAPHNELO autoinjector parts

- **Do not** remove the cap until right before injecting SAPHNELO.
- **Do not** touch the green needle guard.



## Preparing to inject using SAPHNELO autoinjector

### Step 1 – Gather supplies for your injection



See Step 10 for instructions on how to throw away (dispose of) the used SAPHNELO autoinjector.

## Step 2 – Remove SAPHNELO autoinjector from the carton and wait 60 minutes

- Select a clean, well-lit, flat work surface, such as a table.
- **Check the expiry date (EXP) on the carton.**
  - **Do not** use if the expiry date has passed.
- Check the carton for damage.
  - **Do not** use if the carton looks damaged.

Open the carton and remove one SAPHNELO autoinjector by gently grasping the middle of the device.

- Store any remaining SAPHNELO autoinjectors in the carton and return them to the refrigerator.

**Let SAPHNELO autoinjector come to room temperature for 60 minutes before injecting.**

- **Do not** warm SAPHNELO autoinjector in any other way. For example, **do not** warm it in a microwave, hot water, direct sunlight, or near other heat sources.



## Step 3 – Inspect SAPHNELO autoinjector

**Check the expiry date on SAPHNELO autoinjector.**

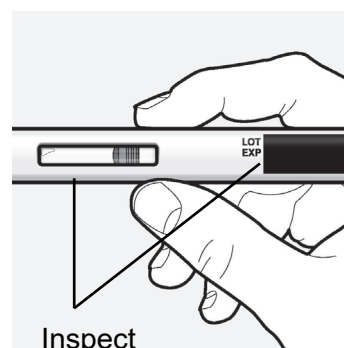
- **Do not** use if the expiry date has passed.

**Check SAPHNELO autoinjector for damage.**

- **Do not** use if damaged.

**Check the liquid through the viewing window.**

- The liquid should be clear and colourless to slightly yellow.
- **Do not** use if the liquid is cloudy, discoloured, or contains visible particles.
- It is normal to see small air bubbles in the liquid. **Do not** try to remove the air bubbles.



## Injecting your SAPHNELO autoinjector

### Step 4 – Choose an injection site

You or your caregiver can inject in the front of your thigh or the lower part of your stomach (abdomen).

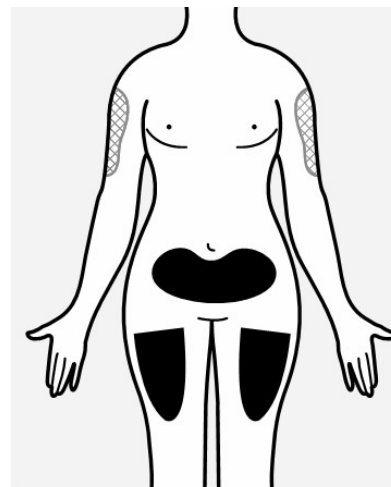
A caregiver may also inject you in your upper arm.

**Do not** try to inject yourself in the upper arm.

Choose an injection site that is at least 3 cm away from where you last injected.

**Do not** inject:

- into the 5 cm area around your belly button.
- where the skin is red, warm, tender, bruised, scaly, or hard.
- into scarred, damaged, discoloured, or tattooed skin.
- through clothing.



 Injection by caregiver

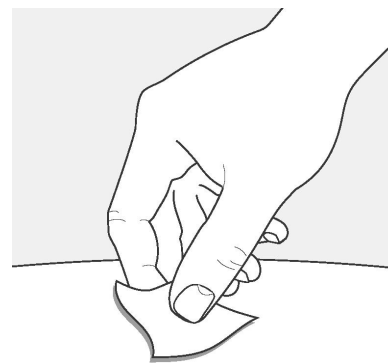
 Self-injection or by caregiver

### Step 5 – Wash your hands and clean the injection site

Wash your hands well with soap and water.

Clean the injection site with an alcohol wipe or with soap and water. Let the site air dry.

- **Do not** touch the cleaned injection site again or blow on it before injecting.



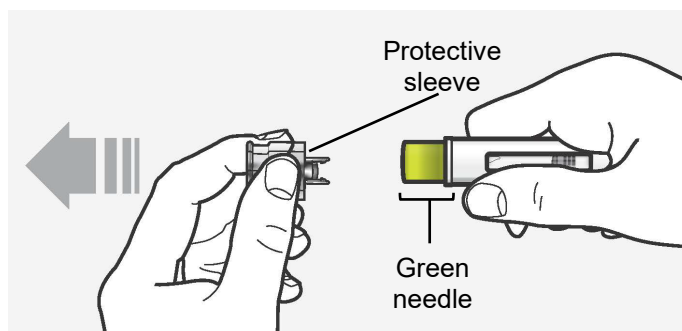
## Step 6 – Pull off the cap

**Do not** remove the cap until you are ready to inject.

Pull off the cap.

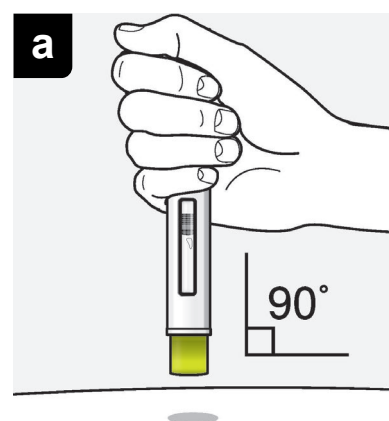
- SAPHNELO autoinjector is now unlocked and ready to inject.
- **Do not** touch the green needle guard or the needle inside.
- **Do not** recap SAPHNELO autoinjector. This could cause the medicine to come out too soon or damage SAPHNELO autoinjector.

Go to Step 7 right away after removing the cap.



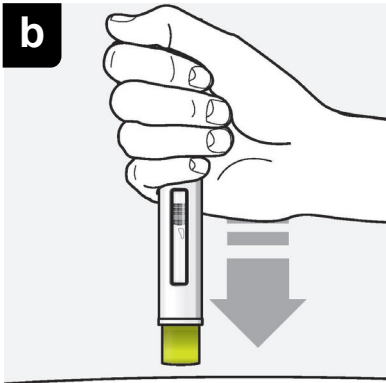
## Step 7 – Injecting SAPHNELO

- Inject using SAPHNELO autoinjector by following the steps in figures **a**, **b**, **c**, and **d**.
- To deliver a full dose, **press and hold SAPHNELO autoinjector for about 15 seconds** until the green plunger fills the viewing window.
- You may hear a **first ‘click’** at the start of the injection and a **second ‘click’** at the end of the injection.
- **Do not** move or change the position of SAPHNELO autoinjector after the injection has started.



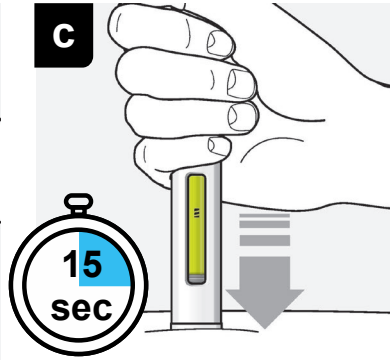
### Position SAPHNELO autoinjector.

- Place the green needle guard flat against the skin (90-degree angle).
- Make sure you can see the viewing window.



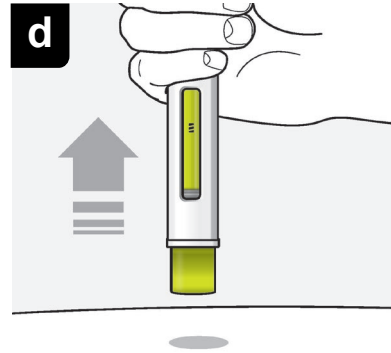
**Press down firmly and hold against skin.**

- You may hear the **first 'click'** right away. This tells you the injection has started.
- The green plunger will move down in the viewing window.



**Hold down firmly for about 15 seconds.**

- The green plunger will fill the viewing window.
- You may hear the **second 'click'** at the end of injection.



**After you have completed your injection, lift SAPHNELO autoinjector straight up.**

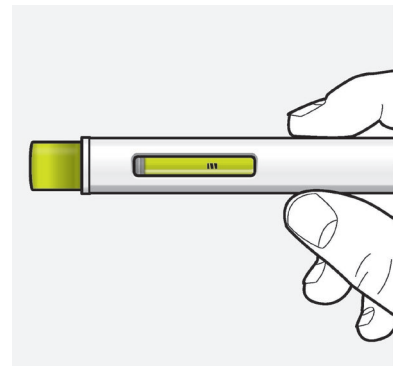
- The green needle guard will slide down and lock into place over the needle.

### Step 8 – Check the viewing window

Check the viewing window to make sure all the medicine has been injected.

If the green plunger does not fill the viewing window, you may not have received the full dose.

- If this happens or if you have any other concerns, contact your healthcare provider.



Before  
injection



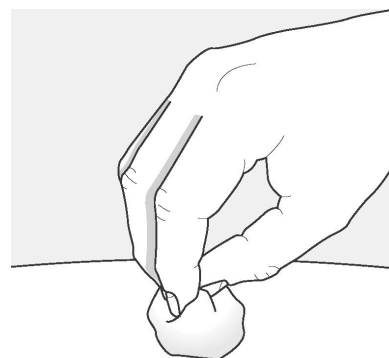
After  
injection

### Step 9 – Check the injection site

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

If needed, press a cotton ball or gauze on the area and apply a small bandage.

- **Do not** rub the injection site.



### Disposing your SAPHNELO autoinjector

#### Step 10 – Throw away (dispose of) the used SAPHNELO autoinjector

Put your used SAPHNELO autoinjector in a **sharps disposal container** right away after use.

**Do not** throw away (dispose of) SAPHNELO autoinjector in your household trash.



### Disposal guidelines

- Dispose of the full container as instructed by your healthcare provider or pharmacist.
- **Do not** dispose of your used sharps disposal container in your household trash unless your community guidelines permit this.
- **Do not** recycle your used sharps disposal container.

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Date of Authorization: 2026-03-23

