DOSING AND ADMINISTRATION

Saphnelo®
(anifrolumab-fnia)
Intravenous Use 300 mg/vial
Subcutaneous Use 120 mg/0.8 mL

What is SAPHNELO?

SAPHNELO is a type 1 interferon receptor antagonist indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy.

Limitations of Use: The efficacy of SAPHNELO has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Use is not recommended in these situations.

Dosage recommendations for SAPHNELO

SAPHNELO is provided as a clear to opalescent, colorless to slightly yellow, solution of anifrolumab-fnia, and is available in single-dose units as:

Vial for intravenous (IV) infusion:
one 300 mg/2 mL (150 mg/mL) vial, diluted and administered **over a 30-minute period, every 4 weeks**

(NDC-00310-3040-00)

Autoinjector SAPHNELO Pen for subcutaneous (SC) injection:
one 120 mg/0.8 mL autoinjector, administered **once every week**

(NDC-00310-3080-01)

Prefilled syringe for SC injection:
one 120 mg/0.8 mL prefilled syringe, administered **once every week**

(NDC-00310-3080-02)

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For the autoinjector and prefilled syringe, a 28-day supply requires prescribing 3.2 mL, equivalent to 4 pens/syringes. Both options will be assigned an NCPDP billing unit of milliliters, with each pen/syringe containing a quantity of 0.8 mL.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

Known history of anaphylaxis with SAPHNELO.

WARNINGS AND PRECAUTIONS

- **Serious Infections:** Serious and sometimes fatal infections have occurred in patients receiving immunosuppressive agents, including SAPHNELO. SAPHNELO increases the risk of respiratory infections and herpes zoster. Use caution in patients with severe or chronic infections. Avoid initiating treatment during an active infection and consider interrupting therapy in patients who develop a new infection during treatment

Please see additional Important Safety Information throughout, and full Prescribing Information, including Patient Information.

Intravenous (IV) administration

Preparing SAPHNELO for IV infusion

Prepare the diluted infusion solution using aseptic technique by the following procedure:

1 | **Do not** shake the vial. Visually inspect the vial for particulate matter and discoloration. SAPHNELO is a clear to opalescent and colorless to slightly yellow solution. **Do not** use and discard the vial if the solution is cloudy, discolored, or contains particles.

2 | Withdraw and discard 2 mL of solution from a 50 mL or 100 mL 0.9% Sodium Chloride Injection, USP infusion bag.

3 | Withdraw 2 mL from the SAPHNELO vial and add to the infusion bag. Mix the solution by gently inverting the bag. **Do not** shake the bag.

4 | Each vial is intended for single use only. Discard any unused portion remaining in the vial.

2 mL

Administering SAPHNELO by IV infusion

5 | Administer the infusion solution immediately after preparation.

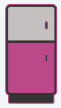
6 | If the infusion solution is not administered immediately after preparation:

- Store the diluted solution of SAPHNELO at room temperature (59 °F to 77 °F [15 °C to 25 °C]) for up to 4 hours. Protect from light

OR

- Refrigerate the diluted solution of SAPHNELO (36 °F to 46 °F [2 °C to 8 °C]) for up to 24 hours. **Do not** freeze. Protect from light. Allow the diluted SAPHNELO solution to reach room temperature prior to administration

59 °- 77 °F



36 °- 46 °F

EVERY 4 WEEKS

7 | **Do not** coadminister other medicinal products through the same infusion line.

8 | Administer the infusion solution IV **over a 30-minute period every 4 weeks** through an infusion line containing a sterile, low-protein–binding, 0.2 to 15 micron in-line or add-on filter.

- **If a serious infusion-related or hypersensitivity reaction (eg, anaphylaxis) occurs, immediately interrupt the administration and initiate appropriate therapy**

9 | To ensure the complete dose of SAPHNELO has been administered, flush the entire infusion line with 25 mL of 0.9% Sodium Chloride Injection, USP at the end of the infusion.

10 | Dispose of any unused medicinal product or waste material in accordance with local requirements.

If a planned IV infusion is missed, administer SAPHNELO as soon as possible. Maintain a minimum interval of 14 days between infusions.

Subcutaneous (SC) administration

Switching between IV and SC routes of administration

From IV to SC	From SC to IV
If transitioning from IV infusion to SC injection, the first SC injection should be administered approximately **2 weeks after the last IV infusion**	If transitioning from SC injection to IV infusion, the first IV infusion should be administered approximately **3-4 weeks after the last SC injection**

SC administration via self-injection

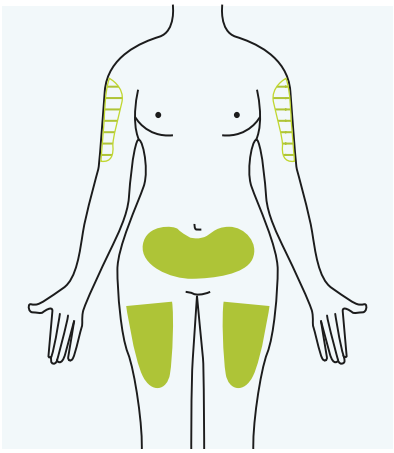
Patients/caregivers may administer SAPHNELO themselves by SC injection after proper training using the SAPHNELO Pen autoinjector or the prefilled syringe.

Choosing an injection site

SAPHNELO can be injected in the front thighs or the lower part of the abdomen. In addition, caregivers may inject SAPHNELO into the upper arm. Injections should be administered at least 1 inch (3 cm) away from where last injected.

DO NOT inject:

- Within 2 inches (5 cm) around the belly button
- Where the skin is red, warm, tender, bruised, scaly, or hard
- Into scarred, damaged, discolored, or tattooed skin
- Through clothing



Self-injection or by caregiver
Injection by caregiver only

The prefilled syringe and autoinjector are not made with natural rubber latex.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

- **Hypersensitivity Reaction Including Anaphylaxis:** Serious hypersensitivity reactions (including anaphylaxis) have been reported following SAPHNELO administration. Events of angioedema have also been reported. Other hypersensitivity reactions and infusion-related reactions have occurred following administration of SAPHNELO. SAPHNELO should be administered by healthcare providers prepared to manage hypersensitivity reactions, including anaphylaxis and infusion-related reactions, if they occur. Immediately interrupt administration and initiate appropriate therapy if a serious infusion-related or hypersensitivity reaction (eg, anaphylaxis) occurs
- **Malignancy:** There is an increased risk of malignancies with the use of immunosuppressants. The impact of SAPHNELO on the potential development of malignancies is not known

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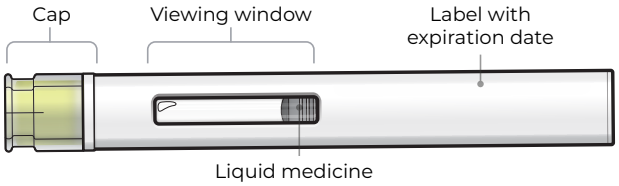
SC administration with the SAPHNELO Pen

Preparing for SC injection using the SAPHNELO Pen autoinjector



1 | Gathering supplies

Advise patients to select a clean, well-lit work surface, such as a table, and collect:

- 1 SAPHNELO Pen from the refrigerator (inspect the carton for damage and check the expiration date)
- 1 alcohol wipe
- 1 cotton ball or gauze
- 1 small bandage
- 1 FDA-cleared sharps disposal container or alternative properly labeled, leak-resistant household container made from heavy-duty plastic and with a tight-fitting puncture-resistant lid

Patients must wait 60 minutes for the product to come to room temperature. They should not warm SAPHNELO in any other way.

DO NOT shake the SAPHNELO Pen or its carton.

DO NOT use if:

- The SAPHNELO Pen or its carton look damaged or if the expiration date on either has passed
- The product has been frozen or exposed to heat

2 | Inspecting the SAPHNELO Pen

- Wash hands well with soap and water
- Open the carton and remove the SAPHNELO Pen by gently grasping the middle of the device
- Using the autoinjector's viewing window, visually inspect the SAPHNELO solution for particulate matter and discoloration prior to administration. SAPHNELO is a clear to opalescent, colorless to slightly yellow, solution. Discard the prefilled syringe or autoinjector if the solution is cloudy, discolored, or visible particles are observed

DO NOT:

- Remove the autoinjector cap until right before injecting SAPHNELO
- Use if the expiration date on the SAPHNELO Pen has passed, or if the device has been dropped, damaged, or appears to have been tampered with
- Use if the liquid within the SAPHNELO Pen is cloudy, discolored, or contains visible particles

SC administration with the SAPHNELO Pen

Administering the SC injection using the SAPHNELO Pen

3 | Preparing the SAPHNELO Pen for injection

Clean the injection site with an alcohol wipe or with soap and water, and let the site air dry. **Do not** touch the cleaned injection site again or blow on it before injecting.

Pull the protective cap off of the SAPHNELO Pen, including its protective sleeve. The SAPHNELO Pen is now ready to use.

DO NOT:

- Touch the green needle guard or the needle inside
- Recap the SAPHNELO Pen

Scan to view the SAPHNELO Pen Instructions for Use video.

4 | Injecting using the SAPHNELO Pen

When using the SAPHNELO Pen, a 'click' may be heard at the start of the injection, and a second 'click' at the end of the injection. **Do not** move or change the position of the SAPHNELO Pen after the injection has started.

- Ensuring the viewing window is visible, **place the green needle guard flat against the skin, forming a 90-degree angle**
- **Press down firmly and hold against the skin;** the green plunger will move down in the viewing area
- **Hold down firmly for approximately 15 seconds,** until the green plunger fills the viewing area
- **After completing the injection, lift the SAPHNELO Pen straight up;** the green needle guard will slide down and lock into place over the needle
- **Check the viewing window to ensure that all medicine has been injected**

Discard the SAPHNELO Pen in an FDA-cleared sharps disposal container.

Inspect the injection site, and if needed, press a cotton ball or gauze on the area and apply a small bandage. **Do not** rub the injection site.

If an SC dose is missed, instruct the patient to administer SAPHNELO as soon as they remember. Thereafter, the patient can start a new weekly schedule from the day the missed dose was administered, or resume dosing on their usual day of administration, provided a minimum interval of 3 days is maintained between SC injections.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

- **Immunization:** Avoid the use of live or live-attenuated vaccines in patients treated with SAPHNELO
- **Use With Biologic Therapies:** SAPHNELO is not recommended for use in combination with other biologic therapies, including B-cell targeted therapies

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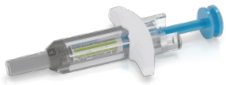
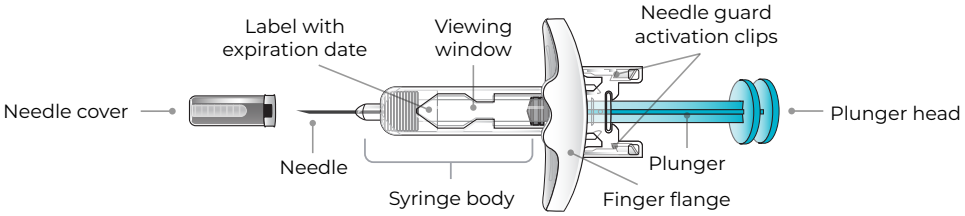
SC administration via SAPHNELO prefilled syringe



Administering the SC injection using the SAPHNELO prefilled syringe



The cleaning of the injection site, gathering of supplies, and disposal requirements for the prefilled syringe are the same as those for the SAPHNELO Pen. Below are the unique steps specific for SC injection using the prefilled syringe.

1 | Inspecting the prefilled syringe

- Open the carton and remove the SAPHNELO prefilled syringe by holding the middle of the syringe body. **Do not** shake the prefilled syringe
- In the prefilled syringe viewing window, visually inspect the SAPHNELO solution for particulate matter and discoloration prior to administration. SAPHNELO is a clear to opalescent, colorless to slightly yellow solution. **Do not** use if the liquid is cloudy, discolored, or contains visible particles or if the needle is damaged or dirty

2 | Preparing the prefilled syringe for injection

- Hold the prefilled syringe body with one hand and carefully pull the needle cover straight off with your other hand. A drop of liquid may be visible at the end of the needle

DO NOT:

- Twist or wiggle the needle cover to remove it
- Touch or pull the plunger or plunger head while removing the needle cover
- Touch the needle or let it touch any surface

3 | Injecting SAPHNELO using the prefilled syringe

- Fully insert the needle of the prefilled syringe into pinched skin at a **45-degree angle; do not** reposition the syringe after insertion
- Push down on the plunger head with your thumb, and keep pushing firmly on the plunger until the SAPHNELO solution is fully injected and the needle guard is activated
- Slowly let go of the plunger until the needle guard covers the needle
- Minor blood/liquid at site is normal. **Do not** rub the injection site
- Discard the used SAPHNELO prefilled syringe in an FDA-cleared sharps disposal container

If an SC dose is missed, instruct the patient to administer SAPHNELO as soon as they remember. Thereafter, the patient can start a new weekly schedule from the day the missed dose was administered, or resume dosing on their usual day of administration, provided a minimum interval of 3 days is maintained between SC injections.

Storing SAPHNELO Pen and prefilled syringe

Storage and handling Instructions

- Keep the SAPHNELO Pen or prefilled syringe in its original carton, protected from light
- Store in a refrigerator at 36 °F to 46 °F (2 °C to 8 °C) in the original carton to protect from light
- **Do not** freeze, expose to heat, or shake
- If needed, an unopened SAPHNELO Pen or prefilled syringe carton can be stored at room temperature (68 °F to 77 °F [20 °C to 25 °C]) **for up to 7 days in the original carton** to protect from light
  - Once the SAPHNELO Pen or prefilled syringe has been removed from the refrigerator and has reached room temperature (68 °F to 77 °F [20 °C to 25 °C]), it must be used within 7 days or discarded. Do not return the SAPHNELO Pen to the refrigerator
- Discard the pen if dropped, damaged, or tampered with

IMPORTANT SAFETY INFORMATION (CONT'D)

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥5%) are nasopharyngitis, upper respiratory tract infections, bronchitis, infusion-related reactions, herpes zoster and cough.

In the controlled clinical trials, the incidence of infusion-related reactions was 9.4% in patients while on treatment with SAPHNELO and 7.1% in patients on placebo. Infusion-related reactions were mild to moderate in intensity; the most common symptoms were headache, nausea, vomiting, fatigue, and dizziness.

USE IN SPECIFIC POPULATIONS

Pregnancy: A pregnancy exposure registry monitors pregnancy outcomes in women exposed to SAPHNELO during pregnancy. For more information about the registry or to report a pregnancy while on SAPHNELO, contact AstraZeneca at 1-877-693-9268.

There are insufficient data on the use of SAPHNELO in pregnant women to establish whether there is drug-associated risk for major birth defects or miscarriage. Advise female patients to inform their healthcare provider if they intend to become pregnant during therapy, suspect they are pregnant or become pregnant while receiving SAPHNELO.

Lactation: No data are available regarding the presence of SAPHNELO in human milk, the effects on the breastfed child, or the effects on milk production.

Pediatric Use: The safety and efficacy of SAPHNELO in pediatric patients less than 18 years of age has not been established.

You may report side effects related to AstraZeneca products.

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SAPHNELO OFFERS MULTIPLE ADMINISTRATION OPTIONS FOR PERSONALIZED TREATMENT

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(NDC-0310-3040-00)

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NCPDP=National Council for Prescription Drug Programs.

Reference: SAPHNELO [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2026.

AstraZeneca

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