SAPHNELO®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about taking this medicine, speak to your doctor or nurse.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I taking SAPHNELO?

SAPHNELO contains the active ingredient anifrolumab. SAPHNELO is used to treat moderate to severe lupus (systemic lupus erythematosus or SLE) in adults whose disease is not well controlled by standard treatment.

For more information, see Section 1. Why am I taking SAPHNELO? in the full CMI.

2. What should I know before I am given SAPHNELO?

Talk to your doctor if you have ever had an allergic reaction to anifrolumab or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant or plan to become pregnant, or are breastfeeding.

For more information, see Section 2. What should I know before I'm given SAPHNELO? in the full CMI.

3. What if I am taking other medicines?

Tell your doctor or nurse if you are taking, have recently taken, or might take any other medicines.

For more information, see Section 3. What if I am taking other medicines? in the full CMI.

4. How is SAPHNELO given to you?

- SAPHNELO vial - It will be given to you in a hospital or clinic by a doctor or nurse.
- SAPHNELO pre-filled pen - Check with your healthcare provider to decide if you can inject SAPHNELO yourself or if your caregiver can do that for you. More instructions can be found in Section 4. How is SAPHNELO given to you? in the full CMI.

5. What should I know while taking SAPHNELO?

Things you should do	• Remind any doctor, dentist or nurse you visit that you are taking SAPHNELO.

	• Keep your appointments with your doctor so that you do not miss a dose and your progress is monitored.
Things you should not do	• Do not stop taking this medicine suddenly, unless you have discussed this with your doctor.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how SAPHNELO affects you.
Call your doctor straight away if you	• Become pregnant while taking SAPHNELO. • Have an infection while you are being treated with SAPHNELO, have had a serious allergic reaction to SAPHNELO (anaphylaxis), plan to have an immunisation (vaccine), or are diagnosed with cancer.
Looking after your medicine	• SAPHNELO vial will be stored by your healthcare providers at the hospital or clinic

	where you receive treatment. Refer to full CMI for storage of SAPHNELO pre-filled pen.

For more information, see Section 5. What should I know while taking SAPHNELO? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. The most common side effects are headache, feeling sick, being sick, feeling tired or weak and dizziness (infusion-related reaction), rash, redness, itching or swelling of the skin where you have received SAPHNELO (hypersensitivity). The more serious side effects are fever or flu-like symptoms, body aches, cough, chest pain, shortness of breath, wheezing or sore throat (infection of the nose, throat, airways or chest, sinuses or lungs), red skin rash that can cause pain and burning (shingles).

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems

SAPHNELO®

Active ingredient: anifrolumab

Consumer Medicine Information (CMI)

This leaflet provides important information about taking SAPHNELO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking SAPHNELO.**

Where to find information in this leaflet:

1. Why am I taking SAPHNELO?
2. What should I know before I am given SAPHNELO?
3. What if I am taking other medicines?
4. How is SAPHNELO given to you?
5. What should I know while taking SAPHNELO?
6. Are there any side effects?
7. Product details

1. Why am I taking SAPHNELO?

SAPHNELO contains the active ingredient anifrolumab. SAPHNELO is a monoclonal antibody (a type of specialised 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 is used to treat moderate to severe lupus (systemic lupus erythematosus or SLE) in adults whose disease is not well controlled by standard treatment. You will be given SAPHNELO as well as your usual treatment for lupus.

Lupus is a disease in which the immune system (the system in the body that fights infections) 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.

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 provider to reduce your daily dose of the oral corticosteroids that are needed to help control your lupus.

2. What should I know before I am given SAPHNELO?

Warnings

Do not take SAPHNELO if:

- you are allergic to anifrolumab or any of the ingredients listed at the end of this leaflet

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other conditions
- have a long term infection or if you have an infection that keeps coming back
- get an infection or have symptoms of an infection. Symptoms may include fever or flu-like symptoms, muscle or joint aches, cough, shortness of breath, stinging or burning while urinating, diarrhoea or stomach pain, shingles (a red skin rash that can cause pain and burning)
- think you have had an allergic reaction. Symptoms may include swelling of your face, tongue or mouth, breathing difficulties, feeling faint, dizzy or lightheaded
- have recently had or plan to have an immunisation (vaccine)
- have, or have had, cancer
- if your lupus affects your kidneys or nervous system

- if you are receiving another biologic medicinal product (such as belimumab for your lupus)

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. It is not known if SAPHNELO can harm your unborn baby. Your doctor will decide if you can be given SAPHNELO.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether SAPHNELO is passed into breast milk. Your doctor 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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SAPHNELO.

4. How is SAPHNELO given to you?

SAPHNELO vial

SAPHNELO will be given to you in a hospital or clinic.

- A doctor or nurse will give you SAPHNELO through a drip in your vein (intravenous infusion) over 30 minutes, every 4 weeks.
- The recommended dose is 300 mg.

SAPHNELO pre-filled pen

- Always use this medicine exactly as your healthcare provider has told you. Check with your healthcare provider if you are not sure.
- The recommended dose is 120 mg once a week, given as an injection under the skin (subcutaneous).
- Your healthcare provider will decide if you can inject SAPHNELO yourself or if your caregiver can do that for you. Before you use SAPHNELO, your healthcare provider should show you or your caregiver how to use SAPHNELO pre-filled pen in the right way.

SAPHNELO vial

- Call your doctor as soon as possible to reschedule your appointment if you miss an appointment to get Saphnelo IV.

It is important that you do not miss a dose of SAPHNELO.

SAPHNELO pre-filled pen

- Read the ‘Instructions for Use’ before injecting SAPHNELO and each time you get a refill. There may be new information.
- If you have used more SAPHNELO than you should, talk to your healthcare provider immediately.
- 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 provider.
- If you or your caregiver have any questions, talk to your healthcare provider.

If you stop taking SAPHNELO

- Do not stop treatment with SAPHNELO unless you have discussed this with your doctor.
- If you have any further questions about your treatment, ask your doctor.

5. What should I know while taking SAPHNELO?

Things you should do

- Remind your doctor, dentist or nurse you visit that you are taking SAPHNELO.
- Keep your appointments with your doctor so that you do not miss a dose and your progress is monitored.

Call your doctor straight away if you:

- become pregnant while taking SAPHNELO
- have an infection while you are being treated with SAPHNELO. Your doctor will want to check that your infection is being properly treated. Symptoms may include fever or flu-like symptoms, muscle or joint aches, cough, shortness of breath, stinging or burning while urinating, shingles (a red skin rash that can cause pain and burning).
- have had a serious allergic reaction to SAPHNELO. Symptoms may include swelling of your face, tongue or mouth, breathing difficulties, feeling faint, dizzy or lightheaded.
- plan to have an immunisation (vaccine)
- are diagnosed with cancer

Things you should not do

- Do not stop taking this medicine suddenly, unless you have discussed this with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how SAPHNELO affects you.

It is not expected that SAPHNELO will affect your ability to drive or use any machines or tools. Be careful if you feel tired, dizzy, or have a headache.

Looking after your medicine

Keep out of the reach and sight of children.

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

SAPHNELO vial

SAPHNELO will be stored by your healthcare providers at the hospital or clinic where you receive treatment.

SAPHNELO pre-filled pen

Store in a refrigerator at 2°C - 8°C in the original carton in order to protect from light.

Do not freeze or shake or expose to heat.

If needed, SAPHNELO pre-filled pen may be kept at room temperature up to 25°C for a maximum of 7 days protected from light. Once SAPHNELO pre-filled pen has reached room temperature, do not return to the

refrigerator. Discard if not used within 7 days at room temperature storage.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Other side effects	What to do
• rash, redness, itching or swelling of the skin where you have received SAPHNELO as they may be symptoms of a less severe allergic reaction (hypersensitivity) • headache, feeling sick (nausea), being sick	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Other side effects	What to do
(vomiting), feeling tired or weak (fatigue) and dizziness as they may be symptoms of an infusion-related reaction • joint pain (arthralgia)	

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Serious side effects

Serious side effects	What to do
• swelling of your face, tongue or mouth, breathing difficulties, feeling faint, dizzy or lightheaded as these may be symptoms of a serious allergic reaction (anaphylaxis) • fever or flu-like symptoms, body aches, cough, chest pain, shortness of breath, wheezing or sore throat as they may be symptoms of an infection of the nose, throat, airways or chest	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
(bronchitis), sinuses (sinusitis) or lungs • red skin rash that can cause pain and burning as this may be a symptom of shingles (herpes zoster)	

The above list includes serious side effects that require medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What SAPHNELO vial and pre-filled pen contains

Active ingredient (main ingredient)	anifrolumab
Other ingredients (inactive ingredients)	histidine, histidine hydrochloride monohydrate, lysine hydrochloride, trehalose dihydrate, polysorbate 80, and water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What SAPHNELO looks like

SAPHNELO vial (AUST R 350930)

SAPHNELO is a clear to opalescent, colourless to slightly yellow concentrated solution supplied in a clear vial closed by a rubber stopper with an aluminium seal. There is 1 vial in each pack.

SAPHNELO pre-filled pen (AUST R 484545)

SAPHNELO is supplied as a clear to opalescent, colourless to slightly yellow concentrate solution.

Each pre-filled pen contains 0.8 mL/120 mg of anifrolumab (150 mg/mL).

Each pack contains 1 or 4 pre-filled pens**.

**Not all pack sizes may be available.

Who distributes SAPHNELO

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
Macquarie Park NSW 2113

Telephone: 1800 805 342

This leaflet was prepared in September 2026.

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