

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 will be given to you in a hospital or clinic by a doctor or nurse.

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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Do not stop taking this medicine suddenly, unless you have discussed this with your doctor.
Driving or using machines	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• SAPHNELO will be stored by your healthcare providers at the hospital or clinic where you receive treatment.

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.

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 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

If you miss an appointment to get SAPHNELO

- Call your doctor as soon as possible to reschedule your appointment
- It is important that you do not miss a dose of SAPHNELO

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

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

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
<ul style="list-style-type: none"> • 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 (vomiting), feeling tired or weak (fatigue) and dizziness as they may be symptoms of an infusion-related reaction • joint pain (arthralgia) 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

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
<ul style="list-style-type: none"> • 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 (bronchitis), sinuses (sinusitis) or lungs • red skin rash that can cause pain and burning as this may be a symptom of shingles (herpes zoster) 	<p>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.</p>

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 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 (AUST R 350930) 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.

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 June 2024.

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VV-RIM-04931514 V2.0