

SAPHNELO®

Anifrolumab, 150 mg/mL, concentrate for infusion

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions people ask about **SAPHNELO**. It does not contain all the information that is known about **SAPHNELO**.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **SAPHNELO** against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What SAPHNELO is used for

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.

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

Before you use SAPHNELO

When you must not use it

Do not take **SAPHNELO** if

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

Before you start to use it

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 Side Effects section.

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.

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

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.

How is SAPHNELO given to you?

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

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

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.

While you are using 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.

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.

Ask your doctor or pharmacist to answer any questions you may have.

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 (vomiting), feeling tired or weak (fatigue) and dizziness as they may be symptoms of an infusion-related reaction - joint pain (arthralgia)	Speak to your doctor if you have any of these less serious side effects and they worry you.

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 (bronchitis), sinuses (sinusitis) or lungs - red skin rash that can cause pain and burning as this may be a symptom of shingles (herpes zoster)	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.

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.

Important: This leaflet alerts you to some of the situations when you should call your doctor. Other situations, which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about **SAPHNELO**.

After taking SAPHNELO**Storage**

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

Product description**What SAPHNELO looks like**

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.

Ingredients

Active ingredient (main ingredient)	Anifrolumab
Other ingredients (inactive ingredients)	- histidine, - histidine hydrochloride monohydrate - lysine hydrochloride - trehalose dihydrate

	• polysorbate 80 • water for injections
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Marketed by:

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