

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **SAPHNELO™**

anifrolumab for injection, intravenous infusion

Read this carefully before you start taking **SAPHNELO** and each time you get an infusion. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **SAPHNELO**.

What is SAPHNELO 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 does SAPHNELO work?

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.

What are the ingredients in SAPHNELO?

Medicinal ingredients: 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 forms:

150 mg/mL concentrate solution for infusion. Each 2.0 mL vial contains 300 mg anifrolumab. There is 1 vial 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 or while you are taking 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.

Breast-feeding

- Before you start treatment with SAPHNELO, tell your healthcare professional if you are breast-feeding. 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 breast-feeding, or if you should stop breast-feeding.

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:

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

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 300 mg, administered as an intravenous infusion over a 30 minute period, every 4 weeks.

Overdose:

If you think you, or a person you are caring for, have taken too much SAPHNELO, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss an appointment to get SAPHNELO, call your healthcare professional as soon as possible to reschedule your appointment.

What are 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.

Common side effects in SAPHNELO studies include joint pain and pain in the arms or legs. Uncommon side effects include neck pain, weakness and fatigue.

SAPHNELO can cause a reaction to the infusion or an allergic (*hypersensitivity*) reaction. In most cases these reactions are mild, but occasionally the reaction can be severe, such as anaphylaxis (uncommon, affecting up to 1 in 100 people).

Tell your healthcare professional immediately, or go to the emergency department of your nearest hospital, if you get any of the following symptoms of a serious allergic reaction (anaphylaxis):

- swelling of your face, tongue, or mouth
- and/or breathing difficulties
- fainting, dizziness, feeling lightheaded (due to a drop in blood pressure)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Allergic (hypersensitivity) reactions which may include: <ul style="list-style-type: none"> • Wheezing • Itching • Rash • Hives • Nausea • Headache • Dizziness 		✓	
Chest Pain		✓	
Depression: <ul style="list-style-type: none"> • New or worse depression • New or worse anxiety 		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<ul style="list-style-type: none"> • Trouble sleeping (insomnia) • Other unusual changes in your behaviour or mood 			
Other infections, which may become serious: <ul style="list-style-type: none"> • Fever • Chills • Cough • Pain or burning with urination or urinating often • Vomiting, abdominal pain and/or diarrhea • Earache • Warm, red, or painful skin 		✓	
Shingles (herpes zoster)		✓	
Swelling of limbs	✓		

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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

Storage:

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. Store at 2 to 8°C (in a refrigerator). Do not freeze. Store in the original package in order to protect from light. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Keep out of reach and sight of children.

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 this Patient Medication Information by visiting the Health Canada 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, 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

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