

Saphnelo

Generic name: anifrolumab-fnia [AN-i-FROL-ue-mab]

Dosage form: injection, for intravenous use **Drug class:** Selective immunosuppressants

Medically reviewed by Melisa Puckey, BPharm. Last updated on Feb 10, 2025.

What is Saphnelo?

Saphnelo infusion is a prescription medicine used for moderate to severe systemic lupus erythematosus (SLE or lupus) in adults who are also receiving other lupus medicines. Saphnelo (anifrolumab-fnia) works to reduce the body's immune and inflammatory response, to improve symptoms of SLE. Saphnelo is a monoclonal antibody that works by blocking type I interferon (INF-1) receptors.

SLE is an autoimmune disease that causes pain and inflammation in your body. It is caused by your body's immune system attacking healthy tissue instead of only fighting infections. Often SLE patients have elevated type I interferon stimulation which means too many unnecessary interferon signals are getting through, leading to inflammation in different parts of the body. Saphnelo blocks INF-1 receptors in the immune system, which decreases inflammatory signals and so improves the symptoms of SLE and reduces lupus flares.

Saphnelo is not recommended for severe active lupus nephritis or severe active central nervous system lupus and is not approved for use by anyone younger than 18 years old

Saphnelo infusion was FDA approved on July 30, 2021.

Before receiving Saphnelo

You should not use Saphnelo if you are allergic to the active ingredient anifrolumab-fnia or any of the inactive ingredients in the injection. There is a complete list of ingredients at the bottom of this page.

Before you receive Saphnelo it is important to tell your healthcare provider about all of your medical conditions, especially if you:

- may have an infection or have infections that keep coming back. If you have an infection you
 should not receive Saphnelo unless your doctor or other healthcare provider tells you to. See Side
 Effects section below for a list of infection symptoms.
- have or have had any type of cancer as there is an increased risk of cancer with the use of immunosuppressants.

are receiving other biologic medicines or monoclonal antibodies.

Make sure you are up to date on all vaccines before you start using this medicine. You should not receive live vaccines during treatment with Saphnelo.

Pregnancy

Tell your doctor if you are pregnant or plan to become pregnant as it is not known if Saphnelo will harm your unborn baby.

Saphnelo may affect your baby's immune system, but having SLE during pregnancy may cause complications such as worsened lupus, dangerously high blood pressure (eclampsia), premature birth, miscarriage, or growth problems in the unborn baby. SLE in the mother may also cause lupus or heart problems to develop in the newborn. The benefit of treating SLE may outweigh any risks to the baby.

Pregnancy Exposure Registry. A pregnancy exposure registry monitors pregnancy outcomes in women who have used this medicine. You can find out more information about the Saphnelo pregnancy registry by calling AstraZeneca at 1-877-693-9268.

Breastfeeding

If you are breastfeeding or planning to breastfeed while on Saphnelo you should talk to your healthcare professional, as it is not known if this medicine passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while receiving this medicine.

Saphnelo pregnancy and breastfeeding warnings (more detail)

How will I receive Saphnelo?

- Saphnelo is a solution your healthcare provider will give you through a needle placed in a vein (IV
 or intravenous infusion). It takes about 30 minutes to give you the full dose.
- Saphnelo is usually given once every 4 weeks, but your doctor will decide how often you have this medicine depending on how your body responds to it.
- This medicine helps to control SLE but does not cure it.
- If you miss an appointment, call your healthcare provider as soon as possible to reschedule your appointment.

Dosing information

Usual Saphnelo Adult Dose for Systemic Lupus Erythematosus:

- 300 mg intravenous infusion given over 30 minutes every 4 weeks.
- Available as 300 mg/2 mL (150 mg/mL) single-dose vial.

Comment:

• This medicine is not recommended for patients with severe active lupus nephritis or severe active central nervous system lupus as the efficacy in these patients has not been evaluated.

What happens if I miss a dose?

Call your doctor for instructions if you miss an appointment for your injection.

If a planned infusion of this medicine is missed, it should be given as soon as possible, but maintain a minimum interval of 14 days between infusions.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

① Detailed Saphnelo dosage information

Saphnelo side effects

Common side effects of Saphnelo may include:

- upper respiratory infections
- · infusion reactions
- cough
- bronchitis
- shingles (herpes zoster)

Saphnelo may cause serious side effects, including:

Serious Infections. This medicine can lower the ability of your immune system to fight infections. You may be at a higher risk of developing respiratory infections and shingles (herpes zoster) during treatment. Infections could be serious, leading to hospitalization or death. Tell your healthcare provider right away if you have any of the following symptoms of an infection:

- fever, sweating, or chills
- muscle aches
- cough
- · shortness of breath
- burning when urinating
- · urinating more often

- · diarrhea or stomach pain
- warm, red, or painful skin or sores on your body.

Allergic (hypersensitivity) reactions, including anaphylaxis. Serious allergic reactions can happen during or after you get your infusion. Tell your healthcare provider or get emergency help right away if you have any of the following symptoms of a serious allergic reaction:

- swelling of your face, mouth, and tongue
- · fainting or dizziness
- breathing problems
- feeling lightheaded (low blood pressure)

Cancer. Saphnelo may reduce the activity of your immune system. Medicines that affect the immune system may increase your risk of certain cancers.

These are not all of the possible side effects. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Saphnelo side effects (more detail)

Related/similar drugs

Plaquenil

Plaquenil is used to treat or prevent malaria and to treat the symptoms of rheumatoid arthritis ...

Reviews & ratings

6.5 / 10

158 Reviews

Decadron

Decadron is used for addison's disease, adrenal insufficiency, adrenocortical insufficiency ...

Reviews & ratings

4.0 / 10

29 Reviews

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Benly

Benlysta system

Review

7.9 / 10

What should I avoid while receiving Saphnelo?

Avoid receiving a "live" vaccine. The vaccine may not work as well while you are using anifrolumab. Live vaccines include measles, mumps, rubella (MMR), rotavirus, typhoid, yellow fever, varicella (chickenpox), and zoster (shingles).

What other drugs will affect Saphnelo?

Many drugs can interact with Saphnelo, and some drugs should not be used at the same time. Tell your doctor about all other medicines you use. This includes prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible interactions are listed here.



Storage

- 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. Do not shake.

What are the ingredients in Saphnelo?

Active ingredient: anifrolumab-fnia

Inactive ingredients: L-histidine, L-histidine hydrochloride monohydrate, L-lysine hydrochloride, trehalose dihydrate, polysorbate 80 and Water for Injection.

Manufacturer

- Manufactured by: AstraZeneca AB Södertälje, Sweden SE-15185.
- Distributed by: AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850.

Saphnelo Biosimilars

Biosimilar and interchangeable products are biological products that are highly similar to and have no clinically meaningful differences from the reference product.

Reference products

These are biological products that have already been approved by the FDA, against which biosimilar products are compared. There is 1 for Saphnelo.

Saphnelo (anifrolumab-fnia) - AstraZeneca AB

Formulation type	Strength
Single-Dose Vial	300 mg/2 mL (150 mg/mL)

Popular FAQ

How long does it take for Saphnelo to work?

What is the difference between Benlysta and Saphnelo?

Is Saphnelo a chemo drug or immunosuppressant?	
How long does a Saphnelo infusion take?	~

References

- 1. Food and Drug Administration (FDA) Saphnelo Product Label
- 2. Trial of Anifrolumab in Active Systemic Lupus Erythematosus

Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.