

**PATIENT INFORMATION**  
**SAPHNELO™ (saf-NEH-low)**  
**(anifrolumab-fnia)**  
**injection, for intravenous use**

**What is SAPHNELO?**

- SAPHNELO is a prescription medicine used to treat adults with moderate to severe systemic lupus erythematosus (SLE or lupus) who are receiving other lupus medicines.
- SAPHNELO contains anifrolumab-fnia which is in a group of medicines called monoclonal antibodies. Lupus is a disease of the immune system (the body system that fights infection). When given together with other medicines for lupus, SAPHNELO may help to reduce your lupus disease activity more than other lupus medicines alone.
- It is not known if SAPHNELO is effective in people with severe active lupus nephritis or central nervous system lupus.
- It is not known if SAPHNELO is safe and effective in children under 18 years of age.

**Do not use SAPHNELO if you:**

- are allergic to anifrolumab-fnia or any of the ingredients in SAPHNELO. See the end of this Patient Information leaflet for a complete list of ingredients in SAPHNELO.

**Before you receive SAPHNELO, tell your healthcare provider about all of your medical conditions, including if you:**

- think you have an infection or have infections that keep coming back. You should not receive SAPHNELO if you have an infection unless your healthcare provider tells you to. See “**What are the possible side effects of SAPHNELO?**”
- are scheduled to receive a vaccination or if you think you may need a vaccination. You should not receive live vaccines during treatment with SAPHNELO.
- have or have had any type of cancer.
- are receiving other biologic medicines or monoclonal antibodies.
- are pregnant or plan to become pregnant. It is not known if SAPHNELO will harm your unborn baby. Tell your healthcare provider if you are pregnant, think you might be pregnant, or plan to become pregnant during your treatment with SAPHNELO.
  - **Pregnancy Exposure Registry.** If you become pregnant while receiving SAPHNELO, talk to your healthcare provider. A pregnancy exposure registry monitors pregnancy outcomes in women exposed to SAPHNELO. You can find out more information about the registry by calling AstraZeneca at 1-877-693-9268.
- are breastfeeding or plan to breastfeed. It is not known if SAPHNELO passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while receiving SAPHNELO.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. SAPHNELO may affect the way other medicines work, and other medicines may affect how SAPHNELO works.

**How will I receive SAPHNELO?**

- Your healthcare provider will give you SAPHNELO through a needle placed in a vein (IV or intravenous infusion). It takes about 30 minutes to give you the full dose of SAPHNELO.
- SAPHNELO is usually given 1 time every 4 weeks.
- If you miss an appointment, call your healthcare provider as soon as possible to reschedule your appointment.

**What are the possible side effects of SAPHNELO?****SAPHNELO may cause serious side effects, including:**

- **Serious Infections.** SAPHNELO 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 with SAPHNELO. 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:
 

<ul style="list-style-type: none"> <li>• fever, sweating, or chills</li> <li>• muscle aches</li> <li>• cough</li> <li>• shortness of breath</li> </ul>	<ul style="list-style-type: none"> <li>• burning when urinating</li> <li>• urinating more often</li> <li>• diarrhea or stomach pain</li> <li>• warm, red, or painful skin or sores on your body.</li> </ul>
--	---

- **Allergic (hypersensitivity) reactions**, including anaphylaxis. Serious allergic reactions can happen during or after you get your SAPHNELO 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
  - breathing problems
  - fainting or dizziness
  - 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.

**The most common side effects of SAPHNELO include:**

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

These are not all of the possible side effects of SAPHNELO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**General information about the safe and effective use of SAPHNELO**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. If you would like more information about SAPHNELO, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about SAPHNELO that is written for health professionals.

**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.

Manufactured by: AstraZeneca AB Södertälje, Sweden SE-15185

Distributed by: AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850

©AstraZeneca 2021

For more information, go to <https://www.SAPHNELO.com> or call 1-800-236-9933.