# Anifrolumab-fnia (Saphnelo®)

Anifrolumab (Saphnelo) is a human IgG1κ monoclonal antibody that binds to the subunit 1 of the type I interferon receptor (IFNAR). This binding inhibits type 1 IFN signaling, thereby blocking biologic activity of type 1 IFNs. Anifrolumab also induces the internalization of IFNAR1, thereby reducing the levels of cell surface IFNAR1 available for receptor assembly. Blockade of receptor mediated type I IFN signaling inhibits IFN responsive gene expression as well as downstream inflammatory and immunological processes. Inhibition of type I IFN blocks plasma cell differentiation and normalizes peripheral T-cell subsets. Type I IFNs play a role in the pathogenesis of SLE. Approximately 60-80% of adult patients with active SLE express elevated levels of type I IFN inducible genes.

## Resources from Manufacturer

Patient Medication Guide

Full Prescribing Information

Saphnelo Co-Pay Assistance Program

AstraZeneca (Az&Me) Patient Assistance Program

## Indications and Dosing in Rheumatology

**Anifrolumab-fnia is indicated for:**

- Adults with moderate to severe systemic lupus erythematosus (SLE) who are receiving standard therapy.
- The efficacy of anifrolumab-fnia has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus, thus use is not recommended in these situations.

**Dosing**

- 300 mg administered as an intravenous infusion over 30 minutes every 4 weeks.
- If a planned infusion is missed, administer as soon as possible. Maintain a minimum interval of 14 days between infusions.

## Contraindications

History of anaphylaxis with anifrolumab-fnia.

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## Warnings and Precautions

- Serious Infections–Avoid initiating during an active infection. Consider the individual benefit-risk if using in patient with sever or chronic infections. Consider interrupting therapy if patient develop a new infection during treatment.
- Hypersensitivity reactions including anaphylaxis and angioedema have been reported
- Malignancy–Consider the individual benefit-risk in patients with known risk factors for malignancy prior to prescribing
- Live vaccines–Avoid use
- Not recommended to use with other biologic therapies

## Adverse Reactions (≥ 5%)

- Nasopharyngitis
- Upper respiratory tract infections
- Bronchitis
- Infusion related reactions
- Herpes zoster
- Cough

## Medication Strength and Preparations

- Solution in single-dose vial (for IV infusion): 300 mg/2 mL

## Medication Administration and Storage

- Store in original carton to protect from light
- Store in refrigerator at 2°C to 8°C (36°F to 46°F)–do not freeze
- Use solution diluted for infusion immediately; may be stored up to 24 hours refrigerated and up to 4 hours at room temperature

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## Intravenous Administration Pre-Infusion Checklist

**Ask the patient if they:**

- Have a current or recent infection or illness.
- Is taking antibiotics.
- Have an upcoming surgery.

If the answer is yes to any of these questions, notify the ordering provider before initiating the infusion therapy.

## Intravenous Medication Preparation

1. Anifrolumab-fnia is supplied as a 300 mg/2 mL single dose vial to be diluted using aseptic technique for intravenous infusion.
2. Withdraw and discard 2 mL of solution from a 50 mL or 100 mL 0.9% NaCl bag, then withdraw 2 mL of solution from anifrolumab-fnia vials and add it to the infusion bag. Mix the solution by gentle inversion. Do not shake.
3. Anifrolumab-fnia solution does not contain preservatives; therefore, unused product remain in the vials should NOT be used.
4. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If particulates and discoloration are noted, the product should not be used.
5. If the infusion solution is not administered immediately, store at room temperature [59 – 79 oF] for up to 4 hours protected from light, or refrigerated [36 – 46 °F] for up to 24 hours. If refrigerated, allow the diluted solution to reach room temperature prior to administration.

## Intravenous Medication Administration and Monitoring

1. Obtain vital signs [temperature, blood pressure and pulse] upon arrival, after initiation of the infusion, upon discontinuing the infusion and before the patient departs the facility.
2. Consider pre-medications before infusion of anifrolumab-fnia for patients with a history of hypersensitivity or infusion-related reactions. The infusion should be administered over 30 minutes through an infusion line containing a sterile, low-protein binding 0.2 to 15 micron in-line or add-on filter.
3. To ensure the complete dose of anifrolumab-fnia has been administered, flush the entire infusion line with 25 mL of 0.9% NaCl at the end of the infusion.
4. Anifrolumab-fnia should not be infused concomitantly in the same intravenous line with other drugs.

## Managing Infusion Reactions

- If a serious infusion-related or hypersensitivity reaction occurs, immediately interrupt the administration and initiate appropriate therapy. Notify the supervising provider of the reaction.

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