Anifrolumab-fnia (Saphnelo®)

Anifrolumab is a human IgG1K 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 systemic lupus erythematosus (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

FDA-Approved Indications and Dosing in Rheumatology

- Anifrolumab-fnia is indicated for the treatment of adult patients with moderate to severe SLE, who are receiving standard therapy.
  - ❑ Limitations of use: The efficacy of anifrolumab-fnia has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Use of anifrolumab-fnia is not recommended in these situations.

Dosing

- 300 mg administered as an intravenous infusion over a 30-minute period 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.

Warnings and Precautions

- Serious Infections–Serious and sometimes fatal infections have occurred in patients receiving anifrolumab-fnia. Anifrolumab-fnia increases the risk of respiratory infections and herpes zoster. Avoid initiating treatment during an active infection. Consider the individual benefit-risk if using in patients with severe or chronic infections. Consider interrupting therapy with anifrolumab-fnia if patients 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 anifrolumab-fnia.
- Avoid use of live or live-attenuated vaccines in patients receiving anifrolumab-fnia.
- Not recommended to use with other biologic therapies.

ACR/ARP Medication Guide

American College of Rheumatology
Empowering Rheumatology Professionals

Association of Rheumatology Professionals
The Interprofessional Division of the American College of Rheumatology

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 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.
- Administer the infusion solution immediately after preparation. If the infusion solution is not administered immediately, store the diluted solution of at room temperature (59°F to 77°F, 15°C to 25°C) for up to 4 hours, or refrigerated (36°F to 46°F, 2°C to 8°C) for up to 24 hours. If refrigerated, allow the diluted anifrolumab-fnia solution to reach room temperature prior to administration.
- Administer the infusion solution intravenously over a 30-minute period through an infusion line containing a sterile, low-protein binding 0.2 to 15 micron in-line or add-on filter.

Updated June 2024–ARP Practice Committee