ACR/ARP Medication Guide

AMERICAN COLLEGE of RHEUMATOLOGY Empowering Rheumatology Professionals

ASSOCIATION of
RHEUMATOLOGY
PROFESSIONALS
The Interprofessional Division of the
American College of Rheumatology

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.

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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.

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DISCLAIMER: The information contained in this biologic reference guide is offered solely for purposes of providing health care professionals with a quick and initial reference. Before prescribing or administering any drug contained in this biologic reference guide, health professionals should read the manufacturer's complete prescribing information in order to be informed of the various clinical considerations to be taken into account. The American College of Rheumatology is providing this information as a benefit and service in furtherance of its educational mission. By providing this information, ACR is not endorsing or recommending any of the listed companies or any of their drugs or other products. The information contained in the biologic reference guides reflect the conclusions of the individual companies and not those of the ACR which specifically disclaims any responsibility or liability for the use of such information and/or for the performance of any of the drugs listed in this biologic reference guide.