

## Anifrolumab (Saphnelo®)

Reduce direct handling to a minimum and wear appropriate personal protective equipment		
CAUTION: High Administration Risk Rating		
Form	300mg concentrate for infusion. Each 2mL vial contains 300mg anifrolumab (150mg/mL)	Store in a refrigerator (2°C - 8°C) in the original package to protect from light.
Reconstitution	Already in solution  MUST be further diluted before administration  Visually inspect the vial for particulate matter and discolouration. Saphnelo is a clear to opalescent, colourless to slightly yellow solution. Discard the vial if the solution is cloudy, discoloured or visible particles are observed.  Do not shake the vial.	
Compatibility & Stability	Sodium Chloride 0.9% <b>ONLY</b>	
Administration	<ul> <li>Withdraw and discard 2 mL of solution from a 50 mL or 100 mL 0.9% sodium chloride injection bag using aseptic technique.</li> <li>Then, withdraw 2 mL (300 mg) of anifrolumab concentrate for injection from the single-use vial, and transfer to the 0.9% sodium chloride injection bag.</li> <li>Gently invert the bag of anifrolumab to mix; do not shake.</li> <li>Infuse over approximately 30 minutes.</li> <li>Use an intravenous infusion set with a 0.2 μ in-line filter. This filter B Braun Sterifix® 0.2μ Ref 4099303 is available to order from stores.</li> </ul>	
Documentation Requirements	Document batch numbers and expiry dates of vials in medical notes.	
Adverse Drug Reactions	Serious hypersensitivity reactions including angioedema including anaphylaxis have been reported following administration of anifrolumab.  In patients with a history of infusion-related reactions and/or hypersensitivity, premedication (e.g., an antihistamine) may be administered before the infusion of anifrolumab.  Anifrolumab increases the risk of respiratory infections and herpes zoster.  Anifrolumab should be used with caution in patients with a chronic infection, a history of recurrent infections, or known risk factors for infection. Treatment with anifrolumab should not be initiated in patients with any clinically significant active infection until the infection resolves or is adequately treated. Patients should be instructed to seek medical advice if signs or symptoms of clinically significant infection occur.	
Disposal	Dispose of infusion bag and administration set in purple-lidded bin.	
Additional Information	Saphnelo is indicated as an add-on therapy for the treatment of adult patients with moderate to severe, active autoantibody-positive systemic lupus erythematosus (SLE), despite standard therapy  Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:  Ireland HPRA Pharmacovigilance Website: <a href="www.hpra.ie">www.hpra.ie</a>	



See **PPG-CUH-CUH-243** Policy Procedure and Guidelines for Management of Patients Attending CUH Infusion Unit for Intravenous Therapy CUH for more information

Information provided relates to Saphnelo® (AstraZeneca)