Eculizumab (Soliris®)

Reduce direct handling to a minimum and wear appropriate personal protective equipment

CAUTION: High Administration Risk Rating

<table>
<tr><td>Form</td><td>300mg in 30ml vial (concentrate for infusion)</td><td>Store in a refrigerator (2°C - 8°C) in the original package to protect from light.</td></tr>
<tr><td>Reconstitution</td><td colspan="2">Already in solution
MUST be further diluted before administration
Do not use if there is evidence of particulate matter or discolouration.</td></tr>
<tr><td>Compatibility & Stability</td><td colspan="2">Sodium Chloride 0.9%
Glucose 5%</td></tr>
<tr><td>Administration</td><td colspan="2">IV Infusion only

Withdraw the total amount of Soliris from the vial(s) using a sterile syringe.
Transfer the recommended dose to an infusion bag.
Dilute Soliris to a final concentration of 5 mg/ml by addition to the infusion bag of suitable diluent.

<table>
<tr><th>Dose and drug volume</th><th>Diluent volume</th><th>Total infusion volume after dilution</th><th>Method of preparation of infusion</th></tr>
<tr><td>300mg (30ml)</td><td>30ml</td><td>60ml</td><td>Remove 70ml from 100ml infusion bag and add 30ml drug solution</td></tr>
<tr><td>600mg (60ml)</td><td>60ml</td><td>120ml</td><td>Remove 190ml from 250ml infusion bag and add 60ml drug solution</td></tr>
<tr><td>900mg (90ml)</td><td>90ml</td><td>180ml</td><td>Remove 160ml from 250ml infusion bag and add 90ml drug solution</td></tr>
<tr><td>1200mg (120ml)</td><td>120ml</td><td>240ml</td><td>Remove 130ml from 250ml infusion bag and add 120ml drug solution</td></tr>
</table>

Gently agitate the infusion bag containing the diluted solution to ensure thorough mixing of the product and diluent.
The diluted solution should be allowed to warm to room temperature prior to administration by exposure to ambient air.
Administered by intravenous infusion over 25 – 45 minutes
Discard any unused portion left in a vial.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
</td></tr>
<tr><td>Documentation Requirements</td><td colspan="2">Document batch numbers and expiry dates of vials in medical notes.</td></tr>
<tr><td>Adverse Drug Reactions</td><td colspan="2">Monitor for headache (occurs in more than 10% of patients)</td></tr>
</table>

This information has been summarised to act as a guide for those administering IV medication. The monograph should be used in conjunction with the drug data sheet and BNF for information on dose, adverse effects, cautions and contra-indications. Further information is available from Pharmacy on 22146 or 22542

	• The use of Soliris increases the patient's susceptibility to meningococcal infection (*Neisseria meningitidis*). Meningococcal disease due to any serogroup may occur. (see additional information below) • Patient to **report fever, headache with fever or neck stiffness** (to out-rule meningitis)
Disposal	Dispose of infusion bag and administration set in purple-lidded bin.
Additional Information	**Eculizumab must NOT be initiated in patients:** • with unresolved Neisseria meningitidis infection • who are not currently vaccinated against Neisseria meningitidis (unless they receive prophylactic treatment with appropriate antibiotics until 2 weeks after vaccination) Dose depends on indication. Soliris is licensed for treatment of Atypical Haemolytic Uremic Syndrome (aHUS),Paroxysmal Nocturnal Haemoglobinuria (PNH), refractory generalised Myasthenia Gravis and Neuromyelitis Optica Spectrum Disorder (NMOSD) 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: www.hpra.ie Give **PATIENT INFORMATION BROCHURE and PATIENT SAFETY CARD** 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 Soliris® (Alexion Pharma)