Maklumat tambahan indikasi untuk upload pada laman web
Year 2016
Products Approved For Additional Indication (DCA 303 – 22 August 2016)

<table>
<tr><th>NO</th><th>PRODUCT
(ACTIVE INGREDIENT)</th><th>ADDITIONAL INDICATION</th><th>MARKETING AUTHORIZATION HOLDER</th></tr>
<tr><td>1.</td><td>1.1 SOLIRIS 300MG/30ML, CONCENTRATE FOR SOLUTION FOR INFUSION
[eculizumab 10mg/ml]</td><td>
➢ Indication:

Soliris is indicated for the treatment of patients with:
Atypical haemolytic uraemic syndrome (aHUS)

➢ Posology:

<u>In Atypical Haemolytic Uraemic Syndrome (aHUS):</u>
<u>Adult Patients:</u>
The aHUS dosing regimen for adult patients (≥18 years of age) consists of a 4 week initial phasefollowed by a maintenance phase:

Initial phase: 900 mg of Soliris administered via a 25 – 45 minute intravenous infusionevery week for the first 4 weeks.
Maintenance phase: 1,200 mg of Soliris administered via a 25 – 45 minute intravenousinfusion for the fifth week, followed by 1,200 mg of Soliris administered via a 25 –45 minute intravenous infusion every 14 ± 2 days.

<u>Paediatric patients:</u>
Paediatric aHUS patients with body weight ≥ 40kg are treated with the adult dosingrecommendations above.

In paediatric aHUS patients with body weight below 40 kg, the Soliris dosing regimen consists of:
<table>
<tr><th>Patient Body Weight</th><th>Initial Phase</th><th>Maintenance Phase</th></tr>
<tr><td>30 to <40 kg</td><td>600 mg weekly x 2</td><td>900 mg at week 3; then 900 mg every 2 weeks</td></tr>
<tr><td>20 to <30 kg</td><td>600 mg weekly x 2</td><td>600 mg at week 3; then 600 mg every 2 weeks</td></tr>
<tr><td>10 to <20 kg</td><td>600 mg weekly x 1</td><td>300 mg at week 2; then 300 mg every 2 weeks</td></tr>
<tr><td>5 to <10 kg</td><td>300 mg weekly x1</td><td>300 mg at week 2; then 300 mg every 3 weeks</td></tr>
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For adults and paediatric aHUS patients supplemental dosing of Soliris is required in the settingof concomitant PE/PI (plasmapheresis or plasma exchange, or fresh
</td><td>DKSH MALAYSIA SDN BHD
B-11-01, The Ascent, Paradigm, No. 1, Jalan SS7/26A, Kelana Jaya
47301 Petaling Jaya Selangor</td></tr>
</table>

frozen plasma infusion):

Type of Plasma Intervention	*Most Recent Soliris Dose*	*Supplemental Soliris Dose With Each Plasma Intervention*	*Timing of Supplemental Soliris Dose*
Plasmapheresis or plasma exchange	*300 mg*	*300 mg per eachplasmapheresis or plasma exchangesession*	*Within 60 minutes after each plasmapheresis orplasma exchange*
	≥600 mg	*600 mg per each plasmapheresis or plasma exchangesession*	
Fresh frozen plasma infusion	*≥300 mg*	*300 mg per infusion of fresh frozen plasma*	*60 minutes prior to each infusion of fresh frozen plasma*

<u>Treatment monitoring</u>
aHUS patients should be monitored for signs and symptoms of thrombotic microangiopathy(TMA) (see section Warning and precaution aHUS laboratory monitoring).
Soliris treatment is recommended to continue for the patient's lifetime, unless the discontinuationof Soliris is clinically indicated.

<u>Method of administration</u>
Do not administer as an intravenous push or bolus injection. Soliris should only be administered viaintravenous infusion as described below.

The diluted solution of Soliris should be administered by intravenous infusion over 25 –45 minutes in adults and 1-4 hours in paediatric patients via gravity feed, a syringe-type pump, oran infusion pump. It is not necessary to protect the diluted solution of Soliris from light during
administration to the patient.

Patients should be monitored for one hour following infusion. If an adverse event occurs duringthe administration of Soliris, the infusion may be slowed or stopped at the discretion of thephysician. If the infusion is slowed, the total infusion time may not exceed two hours in adultsand adolescents (aged 12 years to under 18 years) and four hours in children aged less than12 years.

2.	2.1 **NESP INJECTION PLASTIC SYRINGE 10 mcg/0.5 ml** [Darbepoetin Alfa 10 mg/0.5 mL] 2.2 **NESP INJECTION PLASTIC SYRINGE 20 mcg/0.5 ml** [Darbepoetin Alfa 20 mg/0.5 mL] 2.3 **NESP INJECTION PLASTIC SYRINGE 30 mcg/0.5 ml** [Darbepoetin Alfa 30 mg/0.5 mL] 2.4 **NESP INJECTION PLASTIC SYRINGE 40 mcg/0.5 ml** [Darbepoetin Alfa 40 mg/0.5 mL] 2.5 **NESP INJECTION PLASTIC SYRINGE 60 mcg/0.5 ml** [Darbepoetin Alfa 60 mg/0.5 mL] 2.6 **NESP INJECTION PLASTIC SYRINGE 120 mcg/0.5 ml** [Darbepoetin Alfa 120 mg/0.5 mL] 2.7 **NESP INJECTION PLASTIC SYRINGE 180 mcg/0.5 ml** [Darbepoetin Alfa 180 mg/0.5 mL]	➢ Indication: *Anaemia with myelodysplastic syndrome.* ***<Precautions related to Indications>* *[Anaemia with myelodysplastic syndrome]* 1. *The efficacy and safety of NESP have not been established in patients who are in the intermediate-2 or high risk categories under the International Prognostic Scoring System (IPSS).* 2. *Patients indicated for NESP should be selected based on a full knowledge of the description in the "CLINICAL STUDIES" section, including serum erythropoietin concentration in patients enrolled in clinical studies, as well as adequate understanding of the efficacy and safety of NESP and reference to the academic guidelines and other relevant updates.* ➢ Posology: *DOSAGE AND ADMINISTRATION* *[Anaemia with myelodysplastic syndrome]* *The usual dose of NESP in adults is 240 µg as darbepoetin alfa (genetical recombination), to be administered as a single subcutaneous injection once weekly. The dose should be decreased in view of the degree of anaemic symptoms and the patient's age.* *<Precautions related to Dosage and Administration>* *[Anaemia with myelodysplastic syndrome]* 1. *The efficacy and safety of NESP in combination with other antitumour agents have not been established.* 2. *If cases such as excessive haemopoiesis occur (the haemoglobin concentration exceeds approximately 11 g/dL) and dose reduction is required, the dose should be reduced by approximately 50%. If after dose reduction, the haemoglobin concentration falls (below approximately 9 g/dL) and dose increase is required, the dose should be increased approximately twofold. The dose should not exceed 240 µg as a single injection.* 3. *If the desired improvement in anaemia is not obtained or anaemia is aggravated after administration of NESP, change to another treatment should be considered. The necessity of continued administration of NESP should be assessed at approximately 16 weeks after the initiation of administration. (See CLINICAL STUDIES).*	**SMART MEDICINE SDN. BHD.** No. 2, Jalan SS 13/5 47500 Subang, Selangor