הודעה על החמרה (מידע בטיחות) בעלון לרופא
(מעודכן 05.2013)

אושר – 2.16

תאריך: 21/02/2016

שם תכשיר באנגלית ומספר הרישום: SOLIRIS 144-09-32985-00

שם בעל הרישום: אלקסיון פארמה ישראל בע"מ

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
Hypersensitivity to eculizumab, murine proteins or to any of the excipients listed in section 6.1. Soliris therapy must not be initiated in patients (see section 4.4): - 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).	Hypersensitivity to eculizumab, murine proteins or to any of the excipients listed in section 6.1. Soliris therapy must not be initiated (see section 4.4): in PNH patients: with unresolved *Neisseria meningitidis* infection. who are not currently vaccinated against *Neisseria meningitidis.* in aHUS patients: with unresolved *Neisseria meningitidis* infection. who are not currently vaccinated against *Neisseria meningitidis* or do not receive prophylactic treatment with appropriate antibiotics	**4.3 Contraindications**

	until 2 weeks after vaccination.	
Soliris is not expected to affect the aplastic component of anaemia in patients with PNH. Meningococcal Infection Due to its mechanism of action, the use of Soliris increases the patient's susceptibility to meningococcal infection (*Neisseria meningitidis*). These patients might be at risk of disease by uncommon serogroups (such as X), although meningococcal disease due to any serogroup may occur. To reduce the risk of infection, all patients must be vaccinated at least 2 weeks prior to receiving Soliris unless the risk of delaying Soliris therapy outweigh the risks of developing a meningococcal infection. Patients who are treated with Soliris less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Vaccines against serotypes A, C, Y, W135 and B where available, are recommended in preventing the commonly pathogenic meningococcal serotypes. Patients must be vaccinated or revaccinated according to current national vaccination guidelines for vaccination use. [---] Immunization Prior to initiating Soliris therapy, it is recommended that PNH and aHUS patients should initiate immunizations according to current immunization guidelines. Additionally, all patients must be vaccinated against meningococcus at least 2 weeks prior to receiving Soliris unless the risk of delaying Soliris therapy outweigh the risks of developing a meningococcal infection. Patients who are treated with Soliris less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until	Soliris is not expected to affect the aplastic component of anaemia in patients with PNH. Meningococcal Infection Due to its mechanism of action, the use of Soliris increases the patient's susceptibility to meningococcal infection (*Neisseria meningitidis*). These patients might be at risk of disease by uncommon serogroups (particularly Y, W135 and X), although meningococcal disease due to any serogroup may occur. To reduce the risk of infection, all patients must be vaccinated at least 2 weeks prior to receiving Soliris. PNH patients must be vaccinated 2 weeks prior to Soliris initiation. aHUS patients who are treated with Soliris less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Patients must be re-vaccinated according to current medical guidelines for vaccination use. Tetravalent vaccines against serotypes A, C, Y and W135 are strongly recommended, preferably conjugated ones. [---] Immunization Prior to initiating Soliris therapy, it is recommended that PNH and aHUS patients should initiate immunizations according to current immunization guidelines. Additionally, all patients must be vaccinated against meningococcus at least 2 weeks prior to receiving Soliris. Patients who are treated with Soliris less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. If available, tetravalent, conjugated vaccines are recommended (see Meningococcal Infection).	**4.4 Special warnings and precautions for use**

2 weeks after vaccination. Vaccines against serotypes A, C, Y, W135 and B where available, are recommended in preventing the commonly pathogenic meningococcal serotypes. (see Meningococcal Infection). [---]	[---]	
Soliris should be prepared for administration by a qualified healthcare professional using aseptic technique. [1] Prior to administration, the Soliris solution should be visually inspected for particulate matter and discolouration. *Instructions:* Reconstitution and dilution should be performed in accordance with good practices rules, particularly for the respect of asepsis. 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 (initial concentration divided by 2)[1] by addition to the infusion bag using sodium chloride 9 mg/ml (0.9%) solution for injection, sodium chloride 4.5 mg/ml (0.45%) solution for injection, or 5% dextrose in water, as the diluent. For 300 mg doses, use 30 ml of Soliris (10 mg/ml) and add 30 ml of diluent. For 600 mg doses, use 60 ml of Soliris and add 60 ml of diluent. For 900 mg doses, use 90 ml of Soliris and add 90 ml of diluent. For 1,200 mg doses, use 120 ml of Soliris and add 120 ml of diluent. [1] The final volume of a 5 mg/ml diluted solution is 60 ml for 300 mg doses, 120 ml for 600 mg doses, 180 ml for 900 mg doses and 240 ml for 1,200 mg doses. The solution should be clear and colourless.	Prior to administration, the Soliris solution should be visually inspected for particulate matter and discolouration. *Instructions:* Reconstitution and dilution should be performed in accordance with good practices rules, particularly for the respect of asepsis. 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 using sodium chloride 9 mg/ml (0.9%) solution for injection, sodium chloride 4.5 mg/ml (0.45%) solution for injection, or 5% dextrose in water, as the diluent. The final volume of a 5 mg/ml diluted solution is 60 ml for 300 mg doses, 120 ml for 600 mg doses, 180 ml for 900 mg doses and 240 ml for 1,200 mg doses. The solution should be clear and colourless. 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.	**6.6 Special precautions for disposal and other handling**

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 [18°C – 25°C][1] prior to administration by exposure to ambient air. The diluted solution must not be heated in a microwave or with any heat source other than the prevailing room temperature.[1] Discard any unused portion left in a vial, as the product contains no preservatives. Diluted solution of Soliris may be stored at 2°C – 8°C for up to 24 hours prior to administration, see section 6.3.[1] Any unused medicinal product or waste material should be disposed of in accordance with local requirements.	Discard any unused portion left in a vial, as the product contains no preservatives. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.	