הודעה על החמרה (מידע בטיחות) בעלון לרופא

תאריך: 21/5/14
שם תכשיר באנגלית: Soliris
מספר רישום : 144 09 32985 00
שם בעל הרישום : Alexion Pharma Israel Ltd

ההחמרות מסומנות בצהוב

פרטים על השינוי/ים המבוקש/ים

פרק בעלון	טקסט נוכחי Current	טקסט חדש
4.8 Undesirable effects	**Table 1: Adverse Reactions Reported in 232 patients included in PNH and aHUS clinical trials and in postmarketing reports** **MedDRA System Organ Class** / **Very Common (≥1/10);** / **Common (≥1/100 to <1/10)** / **Uncommon (≥1/1,000 to <1/100)** **Infection and infestations** / / Meningococcal sepsis, Meningococcal meningitis, Sepsis, Septic shock, Pneumonia, Arthritis bacterial Upper respiratory tract infection, , Nasopharyngitis, Bronchitis, Oral Herpes Gastrointestinal infection, , rinary tract infection, Cystitis, Viral infectionl / Neisseria infection, Lower respiratory tract infection, Fungal infection, Haemophilus infection, Abscess, Cellulitis, Influenza, Gingival infection, Infection, Sinusitis, Tooth infection, Impetigo	**Table 1: Adverse Reactions Reported in 232 patients included in PNH and aHUS clinical trials and in postmarketing reports** **MedDRA System Organ Class** / **Very Common (≥1/10);** / **Common (≥1/100 to <1/10)** / **Uncommon (≥1/1,000 to <1/100)** **Infection and infestations** / / Meningococcal sepsis, Meningococcal meningitis, Sepsis, Septic shock, Pneumonia, Arthritis bacterial Upper respiratory tract infection, , Nasopharyngitis, Bronchitis, Oral Herpes Gastrointestinal infection, , rinary tract infection, Cystitis, Viral infectionl / Neisseria infection, Lower respiratory tract infection, Fungal infection, Haemophilus infection, Abscess, Cellulitis, Influenza, Gingival infection, Infection, Sinusitis, Tooth infection, Impetigo

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,	The diluted solution of Soliris should be administered by intravenous infusion over 25 - —45 -minutes via gravity feed, a syringe-type pump,	**4.2 Posology and method of administration**
Other Systemic Infections Due to its mechanism of action, Soliris therapy should be administered with caution to patients with active systemic infections. Patients may have increased susceptibility to infections, especially with encapsulated bacteria. Patients should be provided with information from the Package Leaflet to increase their awareness of potential serious infections and the signs and symptoms of them. [….] Immunogenicity Infrequent antibody responses have been detected in Soliris-treated patients across all clinical studies. In placebo controlled studies low antibody responses have been reported with a frequency (3.4%) similar to that of placebo (4.8%). In patients with aHUS treated with Soliris, antibodies to Soliris were detected in 3/100 (3%) by the ECL bridging format assay. 1/100 (1%) aHUS patients had low positive values for neutralizing	Other Systemic Infections: –Due to its mechanism of action, Soliris therapy should be administered with caution to patients with active systemic infections. Patients should be provided with information from the Package Leaflet to increase their awareness of potential serious infections and the signs and symptoms of them. [….] Immunogenicity -Infrequent, low titre antibody responses have been detected in Soliris-treated patients across all studies. In placebo controlled studies low titre responses have been reported with a frequency (3.4%) similar to that of placebo (4.8%). No patients have been reported to develop neutralizing antibodies following therapy with Soliris, and there has been no observed correlation of antibody development to clinical response or adverse events.	**4.4 Special warnings and precautions for use**

antibodies. There has been no observed correlation of antibody development to clinical response or adverse events.		
Common: **(≥1/100 to <1/10)** **Infection and infestations**: Meningococcal sepsis, Aspergillus infection, Arthritis bacterial, Upper respiratory tract infection, Nasopharyngitis, Bronchitis, Oral Herpes, Urinary tract infection, Viral infection **Metabolism and nutrition disorders**: Decreased appetite **Vascular disorders**: Hypotension		**4.8 Undesirable effects**

Respiratory, thoracic and mediastinal disorders:
Dyspnoea, Cough, Nasal congestion, Pharyngolaryngeal pain, Rhinorrhoea

Musculoskeletal and connective tissue disorders:
Arthralgia, Myalgia, Muscle spasms, Bone pain ,Back pain , Neck pain, Pain in extremity

General disorders and administration site condition:
Oedema, , Chest discomfort, Pyrexia, Chills, Fatigue, Asthenia Influenza like illness

Uncommon (≥1/1,000 to <1/100)

Infection and infestations:
Meningococcal meningitis, Neisseria infection, Sepsis, Septic shock, Pneumonia, Lower respiratory tract infection, Fungal infection, *Haemophilus influenzae* infection, Abscess, Cellulitis, Influenza, Gastrointestinal infection, Cystitis, Gingival infection, Infection, Sinusitis, Impetigo Tooth Infection

עיצב:גופן: לא מודגש, קו תחתון

Description of selected adverse reactions
In all PNH and aHUS clinical studies the most serious adverse reaction was meningococcal septicaemia
Antibodies to Soliris were detected in 2% of patients with PNH using an ELISA assay and 3% of patients with aHUS using the ECL bridging format assay. As with all proteins there is a potential for immunogenicity.

Description of selected adverse reactions
In all PNH clinical studies the most serious adverse reaction was meningococcal septicaemia in two vaccinated PNH patients (see section 4.4). There were no meningococcal infections or deaths in the aHUS clinical studies. Low titres of antibodies were detected in 2% patients with PNH treated with Soliris. As with all proteins there is a potential for immunogenicity.