Guide for Patients/Parents/Caregivers

Drug Substance SOLIRIS® (eculizumab)

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This guide is intended to explain important safety information of SOLIRIS (eculizumab) to patients and parents/caregivers of infants and children who are prescribed Eculizumab and describes:

- What is SOLIRIS (eculizumab)?
- Important safety information related to Eculizumab
- Patient Card
- Important safety information for infants and children who are receiving Eculizumab
- Contact Information

WHAT IS SOLIRIS (ECULIZUMAB)?

eculizumab is used to treat adults and children with:

Eculizumab is indicated in adults and children for the treatment of:

- Paroxysmal nocturnal haemoglobinuria (PNH).

  Evidence of clinical benefit is demonstrated in patients with haemolysis with clinical symptom(s) indicative of high disease activity, regardless of transfusion history.

- Atypical haemolytic uremic syndrome (aHUS).

Eculizumab is indicated in adults for the treatment of:

- Refractory generalized myasthenia gravis (gMG) in patients who are anti-acetylcholine receptor (AChR) antibody-positive (see section 5.1).

Eculizumab must be prescribed by a doctor. For full information, refer to the approved Saudi SPC and PIL

IMPORTANT SAFETY INFORMATION RELATED TO ECULIZUMAB

Risk of Meningococcal infection

- Eculizumab reduces your natural resistance to a certain bacteria called *Neisseria meningitidis* that increases your risk of meningococcal infection. The meningococcal infection can lead to severe swelling of the tissues surrounding the brain and spinal cord (meningitis) and/or a severe infection of the blood (septicaemia, also known as blood poisoning or sepsis).
- These infections require urgent and appropriate care as they may become rapidly fatal or life-threatening or lead to major disabilities.

Before starting treatment with Eculizumab

- Your doctor will vaccinate you against meningococcal infection in accordance with current national guidelines, at least 2 weeks before beginning therapy. You may also need to be revaccinated against meningococcal infection in accordance with current national guidelines. If Eculizumab treatment is initiated less than 2 weeks after receiving the meningococcal

vaccine, your doctor will make sure that you take antibiotics to reduce the risk of infection until 2 weeks after you have been vaccinated.

- Vaccination reduces the risk of developing meningococcal infection, but it does not remove the risk completely. Your doctor might consider that you need additional measures to prevent infection.
- Ask your doctor if you have any questions about the vaccinations you require before starting Eculizumab.

During treatment with Eculizumab:

- Be aware of the signs and symptoms of meningococcal infection and notify your doctor immediately if any of these occur.
- **If you cannot reach your doctor, go to an emergency department and show them your patient card.**

The signs and symptoms of meningococcal infection you must look for are:

- Headache with nausea or vomiting
- Headache with a stiff neck or back
- Fever
- Rash
- Confusion
- Severe muscle aches combined with flu-like symptoms.
- Sensitivity to light

You will be provided with a Patient Card (see below). Please carry this with you at all times throughout the duration of your Eculizumab therapy and for 3 months after the last dose of Eculizumab and show it to any healthcare professional you see.

- The signs and symptoms of meningitis can be different in infants and children. These are described under the important safety information for infants and children who are taking Eculizumab.

Risk of other infections

- Eculizumab treatment may reduce your natural resistance to other similar bacterial infections including gonorrhea which is a sexually transmitted disease.
- Eculizumab therapy is given with caution to patients who have infection in the bloodstream. Before starting Eculizumab, tell your doctor if you have any infections.
- If you know that you are at risk of gonorrhea (a sexually transmitted infection), ask your doctor or pharmacist for advice before using this medicine.

- A doctor will administer a vaccine to a child aged less than 18 years against Haemophilus influenzae and pneumococcal infections according to the national vaccination recommendations for each age group..

If you stop using Eculizumab for aHUS

- Consult the prescriber before stopping Eculizumab or postponing doses.
- Interrupting or ending treatment with Eculizumab may cause your aHUS symptoms to come back.
- Your doctor will discuss the possible side effects with you and explain the risks.
- Your doctor will monitor you closely.
- The risks of stopping Eculizumab include an increase in the inflammation of your platelets (an important part of the blood for clotting), which may cause:
    - A large drop in the number of platelets (thrombocytopenia),
    - A large increase in destruction of your red blood cells (anaemia),
    - Problems with your kidneys (decreased urination),
    - Problems with your kidneys (an increase in your creatinine level),
    - Confusion or change in how alert you are,
    - Chest pain, (angina),
    - Shortness of breath, or
    - Blood clotting (thrombosis).
- If you have any of the above, contact your doctor.

PATIENT CARD

You will receive a Patient Card from your doctor:

- It is very important to rapidly identify and be treated for certain types of infection in patients who receive Eculizumab; therefore, you will be given a card that lists the specific symptoms you must always look for.
- You must carry this card at all times throughout the duration of your Eculizumab therapy and for 3 months after the last dose of Eculizumab and show it to any healthcare professional you see.

IMPORTANT SAFETY INFORMATION FOR INFANTS AND CHILDREN WHO ARE RECEIVING ECULIZUMAB

Meningococcal infections are extremely dangerous and may become life-threatening within hours. Early symptoms of meningitis can include:

- Fever

- Headache
- Vomiting
- Diarrhoea
- Muscle pain
- Stomach cramps
- Fever with cold hands and feet

Common Signs and Symptoms of Meningitis and Severe Blood Infection (Sepsis) in infants and children

- Fever, cold hands and feet
- Fretful, dislike being handled
- Rapid breathing or grunting
- Unusual cry, moaning
- Stiff neck, dislike bright lights
- Refusing food and vomiting
- Drowsy, floppy, unresponsive
- Pale, blotchy skin spots/rash
- Tense, bulging fontanelle (soft spot on the baby's head)
- Convulsions/seizures

In children, additional signs and symptoms to those listed for infants may include:

- Severe muscle pain
- Severe headache
- Confusion
- Irritability

Do not wait for a rash. If your child is ill and getting worse, get medical help immediately.

Meningitis symptoms can appear in any order. Some may not appear at all. It is very important to seek medical care immediately if you see any of the above signs and symptoms.

PAEDIATRIC SAFETY INFORMATION CARD

The Paediatric Safety Information Card contains important safety information that you or anyone responsible for the care of your child should know throughout the duration of your child's Eculizumab therapy and for 3 months after the last dose of Eculizumab.

Fill out the card and give one to anyone responsible for the care of your child (for example a teacher, babysitter/nanny, daycare centre staff). Also, be sure to carry a set with you at all times.

Tell the person responsible for the care of your child that the card should be shown to any healthcare professional involved in the child's treatment, should the child need medical attention.

If the child shows any signs or symptoms of meningitis or severe blood infection (sepsis), contact their healthcare provider immediately.

If you cannot reach the healthcare professional, seek immediate emergency care at an emergency department and show the staff the child's Paediatric Safety Information Card.

CONTACT INFORMATION

If you experience any side effects from your treatment with Eculizumab, please report these to:

AstraZeneca, Saudi Arabia:

Email: ksa.ae@astrazeneca.com

Phone: +966 11 2249235

Portal: https://contactazmedical.astrazeneca.com/

Or SFDA reporting information:

Email: npc.drug@sfda.gov.sa

Toll free phone: 19999

Portal: https: //ade.sfda.gov.sa>

REFERENCES

SOLIRIS (eculizumab) SOLIRIS® 300 mg/30 mlconcentrate for solution for infusion
Eculizumab Patient Information Leaflet

Front of the card

PAEDIATRIC SAFETY INFORMATION CARD

IMPORTANT INFORMATION FOR SUPERVISING INDIVIDUALS

This child is currently being treated with Eculizumab and has reduced natural resistance to infections, especially meningococcal infections, which include meningitis and severe blood infection or blood poisoning (also known as sepsis). If you notice that the child has any of the signs or symptoms listed on this card, which could indicate a serious infection, call the child's doctor immediately.

Patient name:

Parent/Guardian contact information:

Physician name:

If you cannot reach the child's doctor, take the child to the emergency department immediately and show the staff this card. Even if the child has stopped using Eculizumab, keep this card with you for 3 months after the child's last Eculizumab dose.

Physician contact information:

Back of the card

Meningitis can become life-threatening within hours.

If **ANY** signs or symptoms should appear, seek medical attention immediately

Meningitis and severe blood infection (sepsis) symptoms for infants and children:
COMMON SIGNS AND SYMPTOMS:

Fever, cold hands and feet	Fretful, dislikes being handled	Severe muscle pain
Stiff neck, dislikes bright lights	Drowsy, floppy, unresponsive	Severe headache
Rapid breathing or grunting	Unusual cry, moaning	Confusion
Pale, blotchy skin; spots/rash	Tense, bulging fontanelle (soft spot)	Irritability
Refusing food and vomiting	Convulsions/seizures	

IMPORTANT SAFETY INFORMATION FOR HEALTHCARE PROFESSIONALS

This patient was prescribed Eculizumab therapy. Eculizumab is an antibody that inhibits terminal complement activation. Due to its mechanism of action, the use of Eculizumab increases the patient's susceptibility to meningococcal infection (*Neisseria meningitidis*).

Before beginning treatment, this patient should have received a meningococcal vaccine, but they may still be susceptible to meningococcal infections or other general infections. You should carefully monitor the emergence of early signs of meningococcal infection, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

For more information about Eculizumab, please refer to [LOCAL LABEL]. In case of safety concerns, call
AstraZeneca, Saudi Arabia:
Email: ksa.ae@astrazeneca.com
Phone: +966 11 2249235
Portal: https://contactazmedical.astrazeneca.com/
Or SFDA reporting information:
Email: npc.drug@sfda.gov.sa
Toll free phone: 19999
Portal: https: //ade.sfda.gov.sa