

PAEDIATRIC SAFETY INFORMATION CARD

This Document has been approved by the Saudi Food and Drug Authority (SFDA).

IMPORTANT INFORMATION FOR SUPERVISING INDIVIDUALS

- This child is currently being treated with eculizumab and may have 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.
- Meningitis can become life-threatening within hours.
- If **ANY** signs or symptoms should appear, seek medical attention immediately.

PLACE PHOTO OF
CHILD HERE

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.

Patient name: _____

Parent/Guardian contact information: _____

Physician name: _____

Physician contact information: _____

Meningitis and severe blood infection (sepsis) symptoms for infants and children:

COMMON SIGNS AND SYMPTOMS:

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

PAEDIATRIC SAFETY INFORMATION CARD**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.

Some patients have experienced infusion reactions following administration of eculizumab. Common general disorders or administration site conditions include chest discomfort, chills, fatigue, asthenia, infusion-related reaction, oedema, and pyrexia. For more information about eculizumab; please refer to eculizumab SmPC.

To report any side effect(s), please contact:

The National Pharmacovigilance Centre (NPC) - Saudi Food and Drug Authority (SFDA):

SFDA Call Center: 19999

E-mail: npc.drug@sfd.gov.sa

Website: <https://ade.sfd.gov.sa/>



Or

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