SOLIRIS® (eculizumab)

Patient/Parent Information

Important safety information to minimise the risk of serious side effects

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INTRODUCTION

This guide is for adult patients and parents/legal guardians of a child who has been prescribed eculizumab. The guide provides you with important safety information that you must be aware of.

FREQUENTLY ASKED QUESTIONS

WHAT INFORMATION WILL I RECEIVE?

You will receive a starter kit containing:

- Patient Safety Card: The Patient Safety Card lists specific symptoms which you should always look out for – it is vital to be able to rapidly identify and treat certain types of infection in people who receive eculizumab. You/your child should carry this card at all times and show it to any health care professional you/your child see(s).
- Patient Information Brochure.

If you don't have any of the above documentation, you can request it from your doctor.

WHAT STEPS SHOULD I TAKE BEFORE STARTING ECULIZUMAB?

- Ensure you/your child's vaccination status is up to date.
- Be aware of the symptoms associated with infections and what to do if you/your child experience(s) any of these symptoms.
- Ensure that you communicate with your/your child's doctor and follow his/her advice – this ensures that you/your child receives appropriate monitoring when on treatment or if the treatment is discontinued.

I AM A PATIENT / I AM A PARENT/LEGAL GUARDIAN OF A CHILD WHO HAS BEEN PRESCRIBED ECULIZUMAB. WHAT ADDITIONAL SAFETY PRECAUTIONS DO I NEED TO KNOW ABOUT BEFORE COMMENCING TREATMENT?

As eculizumab blocks a part of the immune system it increases the risk of severe infection and sepsis, especially by a type of bacteria called *Neisseria meningitidis*. This can cause cases of meningococcal infection (severe infection of the linings of the brain and/or blood infection and other *Neisseria* infections including disseminated gonorrhoea. To reduce the risk of severe infections, you/your child will need to take certain precautions.

YOU/YOUR CHILD MUST BE VACCINATED AGAINST HAEMOPHILUS INFLUENZA AND PNEUMOCOCCAL INFECTION

To reduce the risk of developing infection you/your child (less than 18 years):

– Must be vaccinated against *Haemophilus influenzae* and pneumococcal infections according to national vaccination guidelines at least 2 weeks before starting eculizumab therapy

Or

– If eculizumab treatment is started less than 2 weeks after you/your child receives these vaccines, then you/your child will be given antibiotics for 2 weeks after you/your child are given the vaccine

If you/your child has not received a meningococcal vaccine or antibiotics, speak to your doctor immediately and before treatment with eculizumab begins.

If the vaccine is not suitable for you/your child (contraindicated), you/your child will be given an antibiotic throughout the treatment period.

You will need to be aware of the signs and symptoms of:

Severe infection

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

Meningitis and sepsis

If you are a parent/legal guardian of an infant or child who is receiving eculizumab, it is important to be aware that signs and symptoms of meningitis and/or sepsis can vary according to your child's age.

In babies, additional signs and symptoms to those listed above may include:

- Rapid breathing
- Cold hands and feet
- Refusing food and/or vomiting
- Unusual crying or moaning
- Baby doesn't like being handled
- Baby is drowsy, floppy or unresponsive

In children additional signs and symptoms to those listed above may include:

- Stiff neck
- Being drowsy or difficult to wake
- Irritability
- Shaking and leg pain

WHEN SHOULD I SEEK URGENT MEDICAL ATTENTION?

Notify your doctor immediately if ANY of the aforementioned symptoms occur.

If you cannot reach your doctor, go to an Accident & Emergency department and show them your/your child's Patient Safety Card.

ARE THERE SERIOUS SIDE EFFECTS WITH ECULIZUMAB?

Allergic reactions

Notify your doctor immediately if any of the following symptoms of severe allergic reaction (anaphylaxis) occur:

- Swelling of the throat and mouth
- Difficulty breathing
- Lightheadedness
- Confusion
- Blue skin or lips
- Collapsing/losing consciousness

WHAT DO I DO IF I/MY CHILD WANT(S) TO STOP TREATMENT?

You must not stop your treatment without medical supervision.

It is very important to make sure that you/your child do/does not miss or postpone any scheduled treatment appointments in order to continue to experience the full benefits of eculizumab therapy.

If you or your child have been prescribed eculizumab to treat atypical haemolytic uraemic syndrome (aHUS), you need to be aware of the following:

- If eculizumab treatment is stopped completely, or postponed (or if treatments are missed), there is a risk that one of the severe complications of your/your child's condition could occur. This complication is called thrombotic microangiopathy. Blood clots form in small blood vessels and this can lead to damage to organs, with the kidney particularly affected in aHUS.

If you or your child have been prescribed eculizumab to treat paroxysmal nocturnal haemoglobinurea (PNH), you need to be aware of the following:

- If eculizumab treatment is stopped completely, or postponed (or if treatments are missed), there is a risk that one of the serious features of your/your child's condition could occur. Haemolysis is a serious feature of PNH – the red cells in the blood that carry oxygen around the body break apart. Haemolysis is linked with many of the symptoms of PNH, and with an increased risk of blood clots forming in key parts of the body.

If you have been prescribed eculizumab to treat refractory generalised Myasthenia Gravis (gMG), or neuromyelitis optica spectrum disorder (NMOSD), you need to be aware of the following:

- If eculizumab treatment is stopped completely, or postponed (or if treatments are missed), there is a risk that the symptoms of your/your child's disease will return (i.e. the condition will relapse) or worsen (i.e. the condition will be exacerbated).

If you plan to stop treatment with eculizumab, you need to discuss beforehand with your/your child's doctor the possible side effects and risks.

PNH & aHUS REGISTRY

To ensure that the care of people with paroxysmal nocturnal haemoglobinuria (PNH) and atypical haemolytic uremic syndrome (aHUS) continues to improve, it is important we have detailed information on the state of health and treatment of as many people with the condition as possible. There are PNH & aHUS registry centres and your physician will provide further details about the registry. The aim of the **PNH & aHUS Registry** is to collect data to characterise the disease and this may provide a better understanding of PNH & aHUS.

Your doctor will also ask you if you would like to participate in the **PNH or aHUS Registry** and will register you if you agree. If this happens you will receive more detailed information about it and be asked to sign a consent form to participate. You will be asked to complete a simple questionnaire about your health and well-being at the beginning and then every 6 months for the duration of the Registry. Your doctor will provide the Registry with some of your medical information such as diagnosis, treatment and medical history.

To include your data in the **PNH or aHUS Registry** your written permission is required. Your participation is entirely voluntary and any information that would allow you to be identified directly or indirectly will be removed so that it cannot be linked to you. Also, you can withdraw your permission at any time.

REPORTING SIDE EFFECTS

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

United Kingdom
In the UK it is easiest and quickest to report side effects online via the Yellow Card website - https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland
In Ireland via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2
Tel: +353 1676 4971 Fax: +353 1676 2517 Website: www. hpra.ie Email: medsafety@hpra.ie

REPORTING SIDE EFFECTS TO THE MANUFACTURER

By reporting side effects, you can help provide more information on the safety of this medicine.
You can report side effects to Alexion, please email: uk.adverseevents@alexion.com
or call: UK: 0800 321 3902. Ireland: 1800 936 544

MORE INFORMATION

If you require further information on eculizumab, please call or email Alexion Medical Information.
Email: medinfo.EMEA@alexion.com Tel: UK: 0800 028 4394 Tel: Ireland: 1800 882 840

HOME HEALTHCARE SERVICE

A Home Healthcare service is available to all patients prescribed eculizumab. For more details, please ask your physician about this service and availability.

GLOSSARY OF TERMS

Anaphylactic reaction

Extreme and severe hypersensitivity reaction affecting the whole body, often starting with itchy rash, throat and/or tongue swelling, shortness of breath, vomiting.

Gonococcal infection

Infection sexually transmitted and caused by the bacterium *Neisseria gonorrhoeae* (also named gonorrhoea). Clinical symptoms and signs can include arthritis (painful inflammation of one or more joints), arthralgias (joint pain), tenosynovitis (painful inflammation surrounding a tendon), and multiple skin lesions. Can disseminate and cause widespread blood infection (sepsis).

Meningococcal infection

Infection caused by the bacterium *Neisseria meningitidis* (also named meningococcus). Can cause meningitis or widespread blood infection (sepsis).

Sepsis

The presence of bacteria (bacteraemia), other infectious organisms, or toxins created by infectious organisms in the bloodstream.

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