ELIZARIA® (ECULIZUMAB)

PATIENT/CAREGIVER'S GUIDE

Important Safety Information to Mitigate the Risk of Serious Side Effects

TABLE OF CONTENTS

INTRODUCTION

This Guide is for adult patients and parents / personal representatives of pediatric patients to whom ELIZARIA® was prescribed. It gives you important safety information about ELIZARIA® to be considered.

FREQUENTLY ASKED QUESTIONS

What information will be provided to me?

Before starting the treatment, you will be given a Starter's kit containing:

- **Patient Safety Card**

  The **Patient Safety Card** lists specific symptoms to be always considered to quickly identify infections that may strike in patients receiving eculizumab and start appropriate treatment. You are / your child is required to always carry this card and present it to any healthcare professional you turn / your child turns for help/advice.

- **Patient/Caregiver's Guide (this document).**

If you do not have these documents, ask your physician for them.

What steps I should take before starting ELIZARIA®?

- Get vaccinated / have your child vaccinated with meningococcal vaccine.
- Understand the symptoms associated with infections and what to do if you experience / your child experiences any of these symptoms.
- Stay in contact with your / your child's physician and follow his/her recommendations. Thus, you will guarantee that you are / your child is being closely monitored while on ELIZARIA® or if the treatment is discontinued.

What additional safety measures I should be aware of before starting ELIZARIA®?

As ELIZARIA® blocks part of your immune system, it increases the risk of serious infections and sepsis, specifically induced by *Neisseria meningitidis* bacterium. This bacterium may cause meningococcal infection (a serious infection of the membranes surrounding the brain) and/or blood infection or other *Neisseria* infections, including disseminated gonorrhea. To mitigate the risk of serious infections, you need / your child needs to take specific precautions.

YOU / YOUR CHILD SHOULD GET VACCINATED AGAINST HAEMOPHILUS AND PNEUMOCOCCAL INFECTIONS

To mitigate the risk of infection, you / your child (under 18 years of age) should

– Get vaccinated against *Neisseria meningitidis* at least 2 weeks before starting ELIZARIA®

– Get vaccinated against *Haemophilus influenzae* and pneumococcal infection in accordance with the national immunization schedule at least 2 weeks before starting ELIZARIA®.

OR

– If ELIZARIA® is started less than 2 weeks after vaccination, you / your child will be receiving antibacterial prophylaxis until 2 weeks after the vaccine dose elapsed.

If you have not / your child has not received meningococcal vaccine or antibacterial prophylaxis, discuss the situation with your / your child's physician before starting ELIZARIA®.

If you / your child may not be vaccinated on medical grounds (e.g., there are contraindications), you / your child should be taking antibiotics during the entire ELIZARIA® treatment period. Discuss the situation with your / your child's physician.

What are the signs and symptoms that should alert me during treatment?

Vaccination can reduce the risk of meningococcal infection, but it does not rule it out completely.

You should be aware of the signs and symptoms of meningococcal infection and notify your / your child's physician immediately if ANY of the following symptoms emerge:

- Headache with nausea or vomiting
- Headache combined with a stiff neck or back
- Fever (a high body temperature)
- Headache and fever
- Fever and rash
- Confusion
- Muscle ache combined with flu-like symptoms
- Sensitivity to light

If you are a parent / personal representative of a pediatric patient receiving ELIZARIA®, you should be aware of the signs and symptoms of meningococcal infection in children that may differ depending on their age.

Young children may additionally present with signs and symptoms as follows:	**Older children** may additionally present with signs and symptoms as follows:
• Rapid breathing • Cold hands and feet • Refusing food and/or vomiting • Unusual cry or moaning • Dislikes being handled • Drowsy, floppy, unresponsive	• Stiff neck • Drowsy, difficult to wake • Irritability • Uncontrollable shaking and leg pain

IF YOU FAIL TO REACH YOUR PHYSICIAN, CALL THE AMBULANCE AND SHOW THE PATIENT SAFETY CARD TO THE AMBULANCE PHYSICIAN.

What other serious side effects may possibly emerge while I am / my child is on ELIZARIA®?

Allergic reactions

ELIZARIA® contains a protein, and any protein may cause allergic reactions. If you experience / your child experiences any signs or symptoms of a severe allergic reaction (anaphylaxis) after receiving ELIZARIA®, urgently contact your / your child's physician:

- Swollen throat and mouth
- Difficulty breathing
- Dizziness
- Confusion
- Blue skin or lips (cyanosis)
- Syncope / fainting fit

IF YOU FAIL TO REACH YOUR PHYSICIAN, CALL THE AMBULANCE AND SHOW THE PATIENT SAFETY CARD TO THE AMBULANCE PHYSICIAN.

What to do if I want / my child wants to discontinue ELIZARIA®?

You / your child may not discontinue ELIZARIA® without medical advice and medical supervision.

You / your child should not miss or delay any scheduled ELIZARIA® treatment visits.

If you are / your child is taking ELIZARIA® to control atypical hemolytic uremic syndrome, you should be aware that

- If the administration of ELIZARIA® is completely discontinued, or delayed, or missed, you are / your child is at risk of a serious complication. This complication is called thrombotic microangiopathy that is characterized by blood clots formed in the smallest blood vessels, which may cause injuries to many of the body's vital internal organs, specifically the kidneys.

If you are / your child is taking ELIZARIA® to control paroxysmal nocturnal hemoglobinuria, you should be aware that

- If the administration of ELIZARIA® is completely discontinued, or delayed, or missed, you are / your child is at risk of a serious complication called hemolysis. Hemolysis is the destruction of red blood cells that carry oxygen to body cells. Hemolysis is associated with multiple manifestations of the disease, including an increased risk of blood clot formation.

If you are / your child is taking ELIZARIA® to control generalized myasthenia gravis or neuromyelitis optica spectrum disorders (NMOSD), you should be aware that

- If the administration of ELIZARIA® is completely discontinued, or delayed, or missed, there is a risk of symptom recurrence (relapsed disorder) or exacerbation (deterioration of the condition).

If you plan to discontinue ELIZARIA®, before doing so you should discuss the possible side effects and risks with your / your child's physician.

REPORTING ELIZARIA® SIDE EFFECTS

If you get any side effects while on ELIZARIA®, both listed and not listed in the Package Leaflet, contact your / or your child's physician.

You can also report any side effects to GENERIUM JSC by emailing at **pv@generium.ru** or calling at **+7 (495) 988-47-94** (Russia).

By reporting side effects, you can help collect more information on ELIZARIA® safety.

GLOSSARY

Anaphylaxis

A severe allergic reaction that is sudden in onset. Anaphylaxis involves the whole body and often starts with pruritic rash, swollen throat and/or tongue, dyspnea or vomiting.

Gonorrhea

A sexually transmitted infection caused by *Neisseria gonorrhoeae* bacterium. The clinical symptoms may include arthritis (a painful inflammation of one or several joints), arthralgia (joint pain), tenosynovitis (a painful inflammation affecting the tendons), and multiple skin lesions. This infection may cause blood infection (sepsis).

Meningococcal infection

An infection induced by *Neisseria meningitidis* bacterium. It may cause meningitis (inflammation of the membranes surrounding the brain) or blood infection (sepsis).

Sepsis

Sepsis (blood infection) is characterized by bacteria, other infectious agents, or their toxins present in the blood flow.

INFORMATION SOURCES

1. Package Leaflet: Information for the Patient – Elizaria®. State Registry of Medicinal Products, LP-No.(000140)-(RG-RU) of 06.08.2024.
2. SOLIRIS® (eculizumab). Patient Guide. What You Need to Know About ULTOMIRIS and SOLIRIS. Approved 03/2024.
3. Резолюция междисциплинарного совета по профилактике тяжелых инфекций у пациентов с генетическими нарушениями регуляции системы комплемента, получающих терапию экулизумабом. *Эпидемиология и Вакцинопрофилактика*. 2017; 92(1): 51-54 (Resolution of the Interdisciplinary Council on the prevention of severe infections in patients with genetic dysregulation of the complement system receiving eculizumab. *Epidemiology and Vaccinal Prevention.* 2017; 92(1): 51-54).

GENERIUM JSC

Registered office address: Building 273,
Zavodskaya St., Volginsky Village,
Petushinsky District, Vladimir Region
601125 Russian Federation
Phone/fax: +7 (49243) 7 25 20
Moscow Office: 10 Testovskaya St.,
entrance 2, Moscow
123112 Russian Federation
Phone/fax: +7 (495) 988 47 94
info@generium.ru / www.generium.ru

NOTES