Refractory gMG Patient information brochure

SOLIRIS®
(eculizumab)

NEOPHARM

ALEXION®
AstraZeneca Rare Disease

This document was last approved in March 2021 by the Israeli Ministry of Health (MOH)

GLOSSARY OF TERMS

Complement system (also known as the complement cascade or just complement)
Part of your immune system that destroys bacteria and other foreign cells.

Generalized Myasthenia Gravis (gMG)
Myasthenia gravis (MG) is a rare, debilitating, neurological disorder in which the body's immune system initiates an attack on the neuromuscular junction. This attack causes tissue damage and impaired neuromuscular transmission, which can manifest in patients as debilitating weakness and/or fatigue.

Gonococcal infection
Infection sexually transmitted and caused by the bacterium *Neisseria gonorrhoea*e (also named gonorrhea).
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).

INTRODUCTION

This guide is for adult patients suffering from refractory generalized Myastenia Gravis (gMG). The guide gives you information about SOLIRIS®, how it will be given to you and about important safety information that you must be aware of.

WHAT IS SOLIRIS®?

SOLIRIS® is a medication that is used to treat adult patients with refractory gMG. It is a type of humanised monoclonal antibody. Antibodies are substances which in the blood can bind to specific targets. Humanised describes the fact that the antibody has been engineered to make it as similar to human antibodies as possible. Monoclonal means that all of the medication comes from one original antibody i.e. they are all exactly the same.

Myasthenia gravis (MG) is a rare, debilitating, neurological disorder in which the body's immune system initiates an attack on the neuromuscular junction. This attack causes tissue damage and impaired neuromuscular transmission, which can manifest in patients as debilitating weakness and/or fatigue.

Many patients with MG initially experience weakness in their ocular (eye) muscles, and the disease typically progresses to the more severe and generalized form to include head, spinal, limb and respiratory muscles. Symptoms can include drooping eyelid, blurred vision, slurred speech, difficulty chewing or swallowing, weakness in the arms and legs, and difficulty breathing, which could lead to a life-threatening myasthenic crisis. Today, approximately 10% to 15% of MG patients are considered refractory—meaning that despite current treatment, they experience intolerable side effects or continue to experience debilitating muscle weakness that severely impairs their ability to engage in simple daily activities such as speaking, swallowing, chewing and even breathing normally.

SOLIRIS® is an antibody which binds to one of the parts of the complement system and makes it inactive. Therefore SOLIRIS® reduces the activity of immune system, which is the cause of the signs and symptoms of gMG. As gMG is a chronic disease, SOLIRIS® is intended as long-term treatment.

FAQs

WHAT ARE THE SAFETY CONSIDERATIONS RELATED TO SOLIRIS®?

IMPORTANT SAFETY INFORMATION

As SOLIRIS® blocks a part of your 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 or/and blood infection) and other Neisseria infections including disseminated gonorrhea.

These infections require urgent and appropriate care as it may become rapidly fatal or life-threatening or lead to major disabilities.

It is important to understand the precautions to take to reduce the risk of these infections and what to do if you are worried you may have an infection (see below).

As a safety precaution:

YOU MUST BE VACCINATED against meningococcal infection before starting SOLIRIS®. If you initiate SOLIRIS® treatment less than 2 weeks after receiving a meningococcal vaccine you must receive an antibiotic until 2 weeks after vaccination to reduce the risk of infection with *Neisseria meningitidis*.

If the vaccine is contra-indicated to you, you will be given an antibiotic throughout the treatment period or until 2 weeks after the vaccine can be given.

WHAT ARE THE SYMPTOMS THAT SHOULD ALERT ME DURING TREATMENT?

Vaccination reduces the risk of developing an infection, but it does not eliminate the risk completely.

You will need to be aware of the signs and symptoms of infection and notify your doctor immediately if ANY of the following symptoms occur:

- 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

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

ARE THERE STEPS I SHOULD TAKE BEFORE STARTING THERAPY?

Prior to commencing treatment, your doctor will discuss with you the importance of:

- Receiving a vaccine against meningitis and in some cases a specific antibiotic to reduce the risk of infection with a type of bacteria called *Neisseria meningitidis*.
- Understanding the symptoms associated with infections and what to do if you experience those symptoms.
- Being carefully monitored by your doctor following any discontinuation of SOLIRIS® treatment.

Your doctor or nurse will make sure you receive receives a vaccine against meningococcal infection at least 2 weeks before your first infusion. If you initiate initiates SOLIRIS® treatment less than 2 weeks after receiving meningococcal vaccine your doctor or nurse will make sure you receive an antibiotic until 2 weeks after vaccination to reduce the risk of infection with *Neisseria meningitidis*.

In addition, you will be closely monitored for meningococcal and other infections during the course of your treatment.

HOW DO I GET STARTED ON SOLIRIS® THERAPY?

SOLIRIS® must be prescribed by a doctor.

You will also be given a starter's kit containing:

- **Patient Safety Card:** it is very important to rapidly identify and treat certain types of infection in patients who receive SOLIRIS®; therefore you will be given a Safety Card which lists specific symptoms for which you should always look out. You should carry this card at all times and show it to any health care professional you see.
- **Refractory gMG Patient information brochure**.

HOW IS SOLIRIS® ADMINISTERED?

SOLIRIS® is administered through an **intravenous infusion** (introduction of a solution into a vein). The infusion lasts **25 to 45 minutes**. It must be prepared and administered by a doctor or other suitably qualified healthcare professional.

As with all drugs administered through an intravenous infusion, SOLIRIS® may cause immediate or delayed reaction. Please refer to your doctor if that happens.

Because there is a risk of infusion reaction (including allergic reaction), following each infusion you will be monitored for about one hour. Your doctor's instructions should be carefully observed.

WHAT DOSE OF SOLIRIS® IS USED?

For adults:

Initial Phase	Maintenance Phase
Every week for the first four weeks, your doctor will administer an intravenous infusion of diluted SOLIRIS®. Each infusion will consist of a dose of 900 mg (3 vials of 30 ml) and will take 25-45 minutes.	In the fifth week, your doctor will administer an intravenous infusion of diluted SOLIRIS® at a dose of 1200 mg (4 vials of 30 ml) over a 25 - 45 minute period. After the fifth week, your doctor will administer 1200 mg (4 vials of 30 ml) every two weeks as a long term treatment.

It is very important to make sure that you **do not miss or postpone any scheduled treatment appointment** in order to continue to control the disease and experience the full benefits of SOLIRIS® therapy.

HOW LONG WILL I NEED TO TAKE SOLIRIS®?

Since refractory gMG **is a chronic disease**, SOLIRIS® is intended to be **an ongoing therapy**.

Patients who start SOLIRIS® should continue receiving SOLIRIS®, even if they feel better.
Interrupting or stopping treatment with SOLIRIS® may cause your refractory gMG symptoms to come back more and possibly worsen after stopping SOLIRIS® treatment.

You must not stop your treatment without medical surveillance

If you plan to stop treatment with SOLIRIS®, you need to discuss beforehand with your doctor the possible side effects and risks.

ARE THERE OTHER CONSIDERATIONS WHILE I AM ON SOLIRIS®?

Infection risk

Due to its mechanism of action, SOLIRIS® should be administered with caution to patients with active systemic infections.

You may also be at risk of other infection with bacteria called Neisseria including disseminated gonococcal infection. If you are at risk of gonorrhea (a sexually transmitted infection), ask your doctor or pharmacist for advice before using this medicine.

Allergic reactions

SOLIRIS® contains a protein and proteins can cause allergic reactions in some people. If you experience any signs or symptoms after receiving SOLIRIS®, you should consult your healthcare professional.

Other medication

It is important to understand that some medications you are taking, should not be changed without consulting your doctor. Please make sure your doctor knows all medications you are taking.

Elderly

There are no special precautions for treated patients aged from 65 years and over.

Undesirable Effects

SOLIRIS® is generally well-tolerated. The most commonly reported side effects were headache, and the most important serious side effect is meningococcal infection. Most headaches were mild and did not persist after the initial administration phase of SOLIRIS®.

REFERENCES

01. SOLIRIS® (eculizumab) prescribing information, as approved by the Israeli MOH.

Provided as a patient educational service by Alexion Pharma Israel

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” that appears on the homepage of the Ministry of Health’s website (www.health.gov.il) which links to a portal, or by the following link:
https://sideeffects.health.gov.il

and by emailing the Registration Holder's Patient Safety Unit at:

drugsafety@neopharmgroup.com

Tel: 1-800-250-255

In addition, please see the SmPC, as approved by the Israeli MoH.

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