



SOLIRIS® (eculizumab)

**Patient/Parent/
Legal Guardian Guide**

Paroxysmal Nocturnal Haemoglobinuria (PNH)

Atypical Haemolytic Uremic Syndrome (aHUS)

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1 INTRODUCTION

SOLIRIS® is used to treat adults and children with:

- Paroxysmal Nocturnal Haemoglobinuria (**PNH**)
- Atypical Haemolytic Uremic Syndrome (**aHUS**)

This guide is to explain important safety information related to SOLIRIS® to patients and parents/legal guardians of infants and children who are prescribed SOLIRIS®

SOLIRIS® must be prescribed by a doctor.

You will receive the following materials from your doctor:

- **Patient 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 card that lists the specific symptoms you must always look for.
 - You must carry this card at all times throughout the duration of your SOLIRIS® therapy and for 3 months after the last dose of SOLIRIS® and show it to any healthcare professional you see.
- **Patient/Parent/Legal Guardian Guide**

2 SAFETY CONSIDERATIONS RELATED TO SOLIRIS®

Risk of Meningococcal infection

- SOLIRIS® may reduce your natural resistance to a certain bacteria called *Neisseria meningitidis* that may increase 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 disabilities².

Before starting treatment with SOLIRIS®:

- ▶ Your doctor will vaccinate you against meningococcal infection, at least 2 weeks before beginning therapy. If SOLIRIS® treatment is initiated less than 2 weeks after receiving 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.
- ▶ Vaccination or revaccination may further activate complement and, as a result, patients with complement-mediated diseases, including PNH and aHUS, may experience increased signs and symptoms of their underlying disease.

Ask your doctor if you have any questions about the vaccinations you require before starting SOLIRIS®

During treatment with SOLIRIS®:

- ▶ Be aware of the signs and symptoms of a meningococcal infection and notify your doctor immediately if any of these occur.

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

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

- ▶ **Carry the patient card at all times throughout the duration of your SOLIRIS® therapy and for 3 months after the last dose of SOLIRIS® and show it to any healthcare professional you see.**

If you cannot reach your doctor, go to an emergency department and show them your patient card.

The signs and symptoms of meningitis can be different in infants and children. These are described under the section Important Safety Information for Infants and Children Who are Receiving SOLIRIS® (Page 7)

Risk of other infections

- SOLIRIS® treatment may reduce your natural resistance to other similar bacterial infections including gonorrhea which is a sexually transmitted disease.
- Before starting SOLIRIS®, tell your doctor if you have any infections.
- If you know that you are at risk of gonorrhea, ask your doctor or pharmacist for advice before using this medicine.
- Your doctor will administer a vaccine to your child aged less than 18 years against *Haemophilus influenzae* and pneumococcal infections according to the national vaccination recommendations for each age group.

Infusion reaction

The treatment will be given to you by your healthcare professional by infusing SOLIRIS® from a drip bag through a tube directly into your vein.

Because there is a risk of reaction during or after the infusion (including allergic reaction), you will be monitored for about one hour following each infusion. Carefully follow the healthcare professional's instructions.

If you experience any discomfort during or after the infusion, please inform your healthcare professional or doctor.

3 HOW LONG WILL I NEED TO TAKE SOLIRIS®?

As you have a chronic disease, SOLIRIS® is intended to be an ongoing therapy.

Do not stop treatment without first discussing with your doctor

If you plan to stop using SOLIRIS® for PNH

Interrupting or stopping treatment with SOLIRIS® may cause your PNH symptoms to come back more severely and sooner.

Your doctor will discuss the possible side effects with you and explain the risks.

Your doctor will monitor you closely for at least 8 weeks.

Stopping SOLIRIS® may lead to increased breakage of your red blood cells, which may cause:

- A large drop in the number of red blood cells (anaemia),
- Confusion or change in how alert you are,
- Chest pain, or angina,
- Problems with your kidneys (an increase in your serum creatinine level) or
- Blood clotting (thrombosis).

If you experience any of the above, contact your doctor.

If you plan to stop using SOLIRIS® for aHUS

Your doctor will discuss the possible side effects with you and explain the risks.

Your doctor will monitor you closely.

Stopping SOLIRIS® may lead to a damage in the small blood vessels in your body and formation of blood clots within these damaged blood vessels, 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 or increased blood creatinine level),
- Confusion or change in how alert you are,
- Chest pain (angina),
- Shortness of breath, or
- Blood clotting (thrombosis).

If you experience any of the above, contact your doctor.

4 IMPORTANT SAFETY INFORMATION FOR INFANTS AND CHILDREN WHO ARE RECEIVING SOLIRIS®

This section is for parents/ legal guardians of infants and young children who are receiving SOLIRIS®.

Meningococcal infections are extremely dangerous and may become life-threatening within hours. Early symptoms of meningitis can include:^{2,3}

- 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^{3,4}

- 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:⁴

- Severe muscle pain
- Severe headache
- Confusion
- Irritability

Do not wait for a rash^{2,3}. If your child is ill and getting worse, get medical help immediately.

Symptoms of meningitis or severe blood infection (sepsis) 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.

If you cannot reach your healthcare professional, seek **immediate** emergency care at an emergency department and show the staff the Patient Card.

FURTHER INFORMATION

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This document has been approved by Singapore Health Sciences Authority (HSA) on 14/06/23.

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3. Signs and symptoms of meningitis in babies and toddlers. Meningitis Now website. Available at: <https://www.meningitisnow.org/meningitis-explained/signs-and-symptoms/signs-and-symptoms-babies-and-toddlers/> (Accessed: 04 November 2022).
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