

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using Soliris?

Soliris contains the active ingredient eculizumab rmc. Soliris is used for the treatment of patients with a disease that affects red blood cells called Paroxysmal Nocturnal Haemoglobinuria (PNH).

Soliris is also used to treat patients with a condition called atypical Haemolytic Uraemic Syndrome (aHUS).

Soliris is also used to treat adult patients with a disease of the central nervous system that mainly affects the eye nerves and the spinal cord called Neuromyelitis Optica Spectrum Disorder (NMOSD).

For more information, see Section [1. Why am I using Soliris?](#) in the full CMI.

2. What should I know before I use Soliris?

Do not use if you have ever had an allergic reaction to Soliris or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Soliris?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Soliris and affect how it works.

See [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Soliris?

Soliris will be given to you directly into the vein (intravenously) by a doctor or nurse. Each infusion will take approximately 25 – 45 minutes in adults, and 1 to 4 hours in paediatric patients.

More instructions can be found in Section [4. How do I use Soliris?](#) in the full CMI.

5. What should I know while using Soliris?

Things you should do	<ul style="list-style-type: none">Remind any doctor, nurse, dentist or pharmacist you visit that you are using Soliris.If you forget or miss a Soliris infusion, call your doctor immediately.
Things you should not do	<ul style="list-style-type: none">Do not stop using this medicine suddenly.Do not stop taking Soliris without checking with your doctor.
Looking after your medicine	<ul style="list-style-type: none">Soliris will be stored in refrigerated conditions (2°C to 8°C) in the hospital or pharmacy.Soliris vials in the original package may be removed from refrigerated storage (up to 25°C) for only one single period of up to 3 days. At the end of this period unopened product can be put back in the refrigerator.

For more information, see Section [5. What should I know while using Soliris?](#) in the full CMI.

6. Are there any side effects?

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

As Soliris blocks part of your immune system, it increases the risk of severe infection and sepsis, especially by a type of bacteria called *Neisseria meningitidis*, which can cause meningitis (major brain inflammation) or a severe infection of the blood (sepsis).

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 [2. What should I know before I start using Soliris](#)) section below or refer to your Patient Safety Information Card).

You must be vaccinated against meningococcal infection (*Neisseria meningitidis*) before starting Soliris.

If you initiate Soliris treatment less than 2 weeks after receiving a meningococcal vaccine you must take antibiotics until 2 weeks after you have been vaccinated to reduce the risk of infection with *Neisseria meningitidis*.

You will need to be aware of the signs and symptoms of meningococcal infections (see [2. What should I know before I start using Soliris](#) section below or refer to your Patient Safety Information Card) and notify your doctor immediately if any of the symptoms occur.

If you cannot reach your doctor, go to Accident and Emergency at your nearest hospital. Show your Patient Safety Information Card to any doctor or nurse who treats you.

Soliris® (so-li-ris)

Active ingredient(s): Eculizumab rmc

Consumer Medicine Information (CMI)

This leaflet provides important information about using Soliris.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Soliris.

Where to find information in this leaflet:

1. Why am I using Soliris?
- [2. What should I know before I use Soliris?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Soliris?](#)
- [5. What should I know while using Soliris?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Soliris?

Soliris contains the active ingredient eculizumab rmc. Soliris is a monoclonal antibody.

Soliris is used for the treatment of patients with a disease that affects red blood cells called Paroxysmal Nocturnal Haemoglobinuria (PNH).

Soliris is also used to treat patients with a condition called atypical Haemolytic Uraemic Syndrome (aHUS).

Soliris is also used to treat adult patients with a disease of the central nervous system that mainly affects the eye nerves and the spinal cord called Neuromyelitis Optica Spectrum Disorder (NMOSD).

Patients with PNH lack naturally occurring protective proteins on the surface of some of their red blood cells. In unaffected individuals, these proteins protect red blood cells from destruction by the body's inflammatory response. PNH patients lack these protective proteins and their red blood cells can be destroyed. This can lead to low red blood cell

counts (anaemia), tiredness, difficulty in functioning, pain, dark urine, kidney failure, shortness of breath and blood clots.

Soliris can block the body's inflammatory response, and its ability to attack and destroy blood cells. In this way Soliris improves anaemia, fatigue, and other signs and symptoms of PNH.

Patients with aHUS have an inflammatory condition which affects the blood system and kidney. This can lead to reduced or lost function of the kidneys or other organs, low blood counts (low platelets and anaemia), tiredness and difficulty functioning. Soliris works by blocking the body's inflammatory response and its ability to attack and destroy its own vulnerable blood and kidney cells.

In patients with NMOSD, the eye nerves, brain and spinal cord are attacked and damaged by the immune system. Soliris is presumed to block the body's inflammatory response, and its ability to attack and destroy its own eye nerves, brain and spinal cord.

2. What should I know before I use Soliris?

Warnings

Soliris treatment may reduce your natural resistance to infections, especially against certain bacteria that can cause meningococcal meningitis (severe infection of the lining of the brain) and sepsis (infection in the blood), as well as other infections caused by similar bacteria (e.g. widespread gonorrhoea).

Do not use Soliris if:

- You are allergic to eculizumab rmc, or any of the ingredients listed at the end of this leaflet
- You have had an allergic reaction to any other proteins of mouse origin

- Symptoms of an allergic reaction may include:
 - shortness of breath, wheezing or difficulty breathing
 - swelling of the face, lips, tongue or other parts of the body
 - rash, itching or hives on the skin

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- you have not been vaccinated against *Neisseria meningitidis*, a bacteria that causes meningococcal infection,
- you are not up to date with your meningococcal vaccination
- if it is less than 2 weeks after receiving your meningococcal vaccination and you are not taking antibiotics to reduce the risk of infection
- you have meningitis

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. [Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Data in a limited number of pregnant women treated with Soliris do not indicate that Soliris increases the risk of harm to the unborn baby; however, your doctor will discuss the risks and benefits with you. Unless you are planning to become pregnant, you should use adequate contraception whilst being treated with Soliris (and up to 5 months after discontinuing treatment).

It is not known whether Soliris passes into breast milk; however, your doctor will discuss the risks and benefits for you and your child if you breastfeed whilst on Soliris treatment.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

The effect of using Soliris on other medicines has not been studied. Ask your doctor or nurse if you have any questions.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Soliris.

4. How do I use Soliris?

How much to take / use

- Soliris will be given to you directly into the vein (intravenously) by a doctor or nurse. Each infusion will take approximately 25 – 45 minutes in adults, and 1 to 4 hours in paediatric patients.
- Soliris has not been studied in children and adolescent patients with NMOSD. Soliris is not for use in this patient population.

- For adults, Soliris is given once a week for the first four weeks, on the fifth week, the dose is increased and then Soliris is given every two weeks thereafter
- For children and adolescents who weigh less than 40kg, Soliris will be given at a frequency and dose that varies depending on their weight
- Children and adolescents who weigh more than 40kg are treated with the adult dosing
- If you are having plasma exchange or plasma infusion you may receive additional doses of Soliris.
- Follow the instructions provided and use Soliris until your doctor tells you to stop.

If you forget to use Soliris

If you forget or miss your appointment for a Soliris infusion, contact your doctor immediately.

If you are given too much Soliris

There have been no reported overdoses of Soliris. As Soliris is given to you under the supervision of your doctor, it is unlikely that you will receive too much.

5. What should I know while using Soliris?

Things you should do

Tell any other doctors, nurses, dentists, and pharmacists who treat you that you are taking this medicine.

Keep appointments with your doctor or clinic.

It is important to have the infusion with Soliris at the appropriate time to make sure the medicine has the best chance of providing treatment for the condition.

Have any tests when your doctor says to.

Your doctor may wish to test your body's response to Soliris or may wish to test your body's response if you stop therapy.

Call your doctor straight away if you:

- Have had an allergic reaction to Soliris, or any of the ingredients listed at the end of this leaflet, or any other proteins of mouse origin.

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Remind any doctor, nurse, pharmacist or dentist you visit that you are using Soliris.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not stop taking Soliris without checking with your doctor.
- If you forget or miss a Soliris infusion, call your doctor immediately.
- If you have PNH, stopping treatment with Soliris may cause a sudden and serious breakdown of your red blood cells.
- Symptoms or problems from red blood cell breakdown include:
 - a large drop in your red blood cell count causing anaemia. Symptoms include tiredness, headaches,

being short of breath when exercising, dizziness and looking pale

- confusion or change in how alert you are
- chest pain or angina
- dark urine
- blood clots
- If you experience any of these symptoms, contact your doctor immediately.
- Your doctor will need to monitor you closely for at least 8 weeks after stopping Soliris.
- If you have aHUS, stopping treatment with Soliris may cause small blood clots (known as thrombotic microangiopathy or TMA). Your doctor will discuss the possible side effects with you and explain the risks. Your doctor will want to monitor you closely.
- Symptoms or problems from TMA may include:
- low blood platelet count, leading to bruising or bleeding more easily than normal
 - a large drop in your red blood cell count causing anaemia. Symptoms include tiredness, headaches, being short of breath when exercising, dizziness and looking pale
 - confusion or change in how alert you are
 - seizures
 - chest pain or angina
 - decreased urination (kidney problems)
 - shortness of breath
 - blood clots
- If you experience any of these symptoms, contact your doctor immediately
- Studies with Soliris did not examine the risk of relapse of NMOSD if treatment with Soliris is discontinued. Hence, the risk of relapse of NMOSD is unknown.
- If you have NMOSD and stop treatment with Soliris, your doctor will need to monitor you closely for signs and symptoms of potential NMOSD relapse.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Soliris affects you.

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

Looking after your medicine

- Soliris will be stored in refrigerated conditions (2°C to 8°C) in the hospital or pharmacy.
- Soliris vials in the original package may be removed from refrigerated storage (up to 25°C) for only one single period of up to 3 days. At the end of this period unopened product can be put back in the refrigerator.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> ● headache ● runny or stuffy nose and colds ● sore throat, mouth ulcers or inflammation of gums ● cough ● chest or lung infection ● difficulty sleeping ● being short of breath (especially when exercising) ● tiredness, unusual weakness or fainting ● flu-like symptoms such as fever, sore throat, cough and chills looking pale ● abnormal dreams ● difficulties or pain when urinating ● dark urine or blood in the urine ● nausea or vomiting ● stomach pain or discomfort ● constipation ● indigestion or an uncomfortable feeling in the stomach or belching after eating ● rash, dry, itchy and inflamed skin ● hair loss ● loss of appetite ● loss of taste ● pins and needles in your hands or feet ● upper respiratory tract infection, cough, throat pain ● ringing in the ears, vertigo, ● cold sores (oral Herpes) ● fatigue ● depression, anxiety, mood swings or sleep disorder ● diarrhoea ● back or neck pain ● spontaneous penile erection 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● severe infection (meningococcal infection, fungal infection (Aspergillus), infection of the lung (pneumonia), kidney infection), sepsis - ● high fever, chills, confusion, rapid breathing, dizziness, light headedness or shakes 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of</p>

66 Talavera Road, Macquarie Park,
NSW 2113

Medical enquiries: 1800 788 189

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Serious side effects	What to do
<ul style="list-style-type: none">serious allergic reaction which causes difficulty in breathing or dizziness (anaphylactic reaction)bleeding or bruising more easily than normalconfusion or change in how alert you aredifficulty breathingchest tightnesschest pain or anginafast or irregular heartbeats, also called palpitationshigh blood pressuremuscle spasms or aching muscles, muscle tenderness or weakness not caused by exercisejoint paininfusion site pain	these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Soliris contains

Active ingredient (main ingredient)	eculizumab rmc
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">sodium chloridemonobasic sodium phosphate monohydratedibasic sodium phosphate heptahydratepolysorbate 80water for injections
Potential allergens	proteins of mouse origin

Do not take this medicine if you are allergic to any of these ingredients.

What Soliris looks like

Soliris is a clear, colourless, solution contained in a 30mL glass vial. (Aust R 138885).

Who distributes Soliris

Alexion Pharmaceuticals Australasia Pty Ltd

Level 4.