

New Zealand Consumer Medicine Information

Soliris[®]

Concentrated solution for intravenous infusion 300mg/mL

What is in this leaflet

This leaflet answers some common questions about Soliris[®].

It does not contain all the available information.

It does not take the place of talking to your doctor or a trained health-care professional.

All medicines have risks and benefits. Your doctor has weighed the risks of you having Soliris[®] against the benefits they expect it will have.

If you have any concerns about this medicine, ask your doctor or nurse.

Keep this leaflet.

You may need to read it again.

What Soliris[®] is used for

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

How it works

Patients with PNH lack naturally occurring protective proteins on the surface of some of their red blood cells. In normal 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, which can lead to low blood counts (anaemia),

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

Soliris[®] binds to a certain protein (C5) in this inflammatory response, blocks part of your immune system, and prevents its ability to attack and destroy its own vulnerable PNH red blood cells. In this way Soliris[®] improves anaemia, fatigue, and other signs and symptoms of PNH.

Before you are given Soliris[®]

When you must not be given Soliris[®]

DO NOT take Soliris[®]

- if you have not been vaccinated against meningococcal infections at least two weeks before taking Soliris[®] or are not up to date with your meningococcal vaccination
- if you have a meningococcal infection

Do not take Soliris[®] if you have a known, severe, life-threatening allergic reaction to:

- Soliris[®]
- any of the ingredients listed at the end of this leaflet

If you are not sure whether you should have Soliris[®], talk to your doctor or nurse.

Before you are given Soliris[®]

You must receive a meningococcal vaccine at least 2 weeks before your first dose of Soliris[®] unless you have already been vaccinated with this vaccine.

If you have been vaccinated with a meningococcal vaccine in the past, you might need a booster dose before starting Soliris[®]. Your doctor will decide if you need another dose of a meningococcal vaccine.

Tell your doctor if you are pregnant or want to become pregnant. There is no information available regarding the use of Soliris[®] in pregnant women. Your doctor will discuss the possible risks and benefits of having Soliris[®] during pregnancy.

Tell your doctor if you are breast-feeding. It is not known whether Soliris[®] passes into breast milk. Your doctor will discuss the possible risks and benefits of having Soliris[®] during breast-feeding.

Tell your doctor if your child is prescribed Soliris[®]. Safety in children has not been studied. If your child is prescribed Soliris[®] you may wish to discuss this with your child's doctor.

Taking other medicines

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

No studies have been carried out on drug interactions with Soliris®.

How Soliris® is given

Soliris® will be given to you once a week for the first five weeks and then every two weeks, directly in to the vein (intravenously) by a trained health care professional.

Your doctor will decide if you need to be dosed more/less often than every two weeks.

If you are given too much (overdose)

There have been no reported overdoses of Soliris®. As Soliris® is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. Following each infusion, you may be monitored for one hour for reactions. If you experience any side effects after being given Soliris®, tell your doctor immediately.

While you are using Soliris®

Things you must do

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® to make sure that it is working or may wish to test your body's response if you stop therapy.

Things you must not do

Do not stop taking Soliris® without checking with your doctor.

If you forget or miss a Soliris® infusion, call your doctor right away.

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
- confusion
- chest pain
- kidney problems
- blood clots

Your doctor will need to monitor you closely for at least 8 weeks after stopping Soliris®.

Things to be careful of

Soliris® is a medicine that affects your immune system. Soliris® can lower the ability of your immune system to fight certain infections. Soliris® increases your chance of getting serious and life-threatening meningococcal infections. A meningococcal vaccine does not prevent all meningococcal infections.

You must be aware of the following signs and symptoms of a meningococcal infection:

- moderate to severe headache with nausea or vomiting
- moderate to severe headache and a fever
- moderate to severe headache with a stiff neck or stiff back
- fever of 39.4°C or higher
- fever and a rash
- confusion
- severe muscle aches with flu-like symptoms, and eyes sensitive to light

Call your doctor or get emergency medical care right away if you have any of the symptoms listed above and listed on the Patient Safety Card.

You will receive a Patient Safety Card that lists the signs and symptoms stated above, and tell you what to do if you have them. Carry it with you at all times. You will need to show the card to any health care provider that treats you.

Side Effects

Serious side effects with Soliris® include:

- **serious and life-threatening infections.** See “Things to be careful of”

Common side effects with Soliris® include:

- headaches
- runny nose and colds
- sore throat
- back pain
- nausea

Call your doctor if you have any of these side effects. These are not all the side effects with Soliris®. Ask your doctor for more information.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Soliris®.

If you get any side effects, do not stop taking Soliris® without first talking to your health care provider.

Ask your doctor or nurse to answer any questions you may have.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you experience any of the following symptoms:

- moderate to severe headache with nausea or vomiting
- moderate to severe headache and a fever
- moderate to severe headache with a stiff neck or stiff back
- fever of 39.4°C or higher
- fever and a rash
- confusion
- severe muscle aches with flu-like symptoms, and eyes sensitive to light

Storing Soliris®

Soliris® will be stored under refrigeration (2°C to 8°C) in the hospital or pharmacy.

Product description

What Soliris® looks like

Soliris® is a clear, colourless, solution contained in a labeled 30 mL glass vial.

Ingredients

Active ingredients

- eculizumab (rnc)

Other ingredients

- Sodium chloride, monobasic sodium phosphate monohydrate, dibasic sodium phosphate heptahydrate, polysorbate 80 and Water for Injection

Manufacturer/Supplier

In Australia:
Alexion Pharmaceuticals
Australasia Pty Ltd
Suite 226-227
117Old Pittwater Road
Brookvale NSW 2100

AUST R 138885

In New Zealand:
Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks Auckland 2022

Telephone: (09) 918 5100

Soliris® is a trademark of Alexion Pharmaceuticals Inc., USA

Date of Preparation: 26 May 2011