▼ 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 .

ULTOMIRIS®

100 mg per 1 mL

Ravulizumab rch

Consumer Medicine Information

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

As Ultomiris 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 meningitis which is a major brain inflammation or a severe infection of the blood.

These infections require urgent and appropriate care as they may become rapidly serious or, fatal 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 Before you start using Ultomiris section below or refer to your Patient Safety Card).

- **You must be vaccinated against meningococcal infection before starting Ultomiris.**
- **If you initiate Ultomiris 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 infection (see Before you start using Ultomiris section below or refer to your Patient Safety 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 Card to any doctor or nurse who treats you.**

What is in this leaflet

This leaflet answers some common questions about Ultomiris. It does not contain all of the available information.

It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you having Ultomiris against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

What Ultomiris is used for

Ultomiris is a medicine containing an active substance called ravulizumab rch which belongs to a class of medicines called monoclonal antibodies.

Ultomiris 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 blood cells. In unaffected individuals, these proteins protect blood cells from damage and 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.

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

Before you are given Ultomiris

When you must not be given Ultomiris

Ultomiris treatment may reduce your natural resistance to infections, especially against certain bacteria that can cause meningococcal disease including meningitis (severe infection of the lining of the brain), sepsis (infection in the blood) or other infections (e.g. widespread gonorrhoea).

DO NOT begin use of Ultomiris if:

- you have not been vaccinated against Neisseria meningitidis, a bacteria that causes meningococcal infection or,
- 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 unresolved meningococcal infection

Do not use Ultomiris if you have had an allergic reaction to:

- Ultomiris, or to any of the ingredients listed at the end of this leaflet
- any other proteins of hamster 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

If you are not sure whether you should be treated with Ultomiris, talk to your doctor or nurse.

Before you start Ultomiris treatment

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

- headache with nausea or vomiting
- headache and a fever
- headache with a stiff neck or stiff back
- fever
- fever and rash
- confusion
- muscle aches with flu-like symptoms

- eyes sensitive to light

Call your doctor immediately and go to Accident and Emergency at your nearest hospital if you have any of the symptoms listed above.

Patient Safety Card

Because of the importance of rapidly identifying meningococcal infection you will be provided with a Patient Safety Card.

You must carry this card with you at all times and show it to any doctor or nurse that treats you.

You must receive a meningococcal vaccine before or at the time of your first dose of Ultomiris or you must take antibiotics to reduce the risk of infection until 2 weeks after you have been vaccinated.

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

You should also be aware that vaccination may not prevent this type of infection.

You may need antibiotics to prevent infection.

Ask your doctor or nurse for advice about gonorrhoea prevention before using this medicine.

Tell your doctor if you have an infection.

Ultomiris may reduce your natural resistance to infection.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Allergic or anaphylactic (more severe allergic) reactions may occur with Ultomiris treatment. Your doctor or nurse will check for side effects during and after your infusion. See "Side Effects" for symptoms to look out for.

Tell your doctor if you are pregnant or want to become pregnant.

Ultomiris has not been studied in pregnant women. Women who are able to get pregnant should use effective contraception methods during treatment, and up to 8 months after treatment.

Tell your doctor if you are breastfeeding.

It is not known whether Ultomiris passes into breast milk. Since many medicines are secreted into breast milk, breastfeeding should be discontinued during treatment, and up to 8 months after treatment.

Tell your doctor if you are on a salt/sodium controlled diet.

Ultomiris contains sodium (main component of cooking/table salt). Each 3mL vial contains 4.6 mg sodium and each 11mL vial contains 16.8 mg sodium.

This may need to be considered in calculating your salt/ sodium intake.

If you have not told your doctor or nurse about any of the above, tell them before you are given Ultomiris.

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.

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

How Ultomiris is given

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Ultomiris will be given to you directly into the vein (intravenously) by a doctor or nurse. The infusion will take approximately 1 hour.

It is recommended that the beginning of your treatment, called the loading phase, extends over 2 weeks. You will have one single Ultomiris infusion (the loading dose) at the beginning of this loading phase.

Two weeks after receiving your loading dose, you will be given Ultomiris once every 8 weeks. This is called the maintenance phase.

The doses administered are based on your body weight; your doctor will calculate this.

If you were receiving Soliris® prior to receiving Ultomiris, the loading dose should be given 2 weeks after the last Soliris infusion.

If you miss a dose

If you forget or miss your appointment for an Ultomiris infusion, contact your doctor immediately.

If you are given too much (overdose)

There have been no reported overdoses of Ultomiris. As Ultomiris is given to you under the supervision of your doctor, it is unlikely that you will receive too much. However, if you experience any side effects after being given Ultomiris, tell your doctor immediately.

While you are using Ultomiris

Things you must do

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

Carry your Patient Safety Card with you at all times and show it to any doctor or nurse that treats you.

Keep all of your doctor's appointments so that your progress can be checked.

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

Things you must not do

Do not stop taking Ultomiris without checking with your doctor.

If you forget or miss an Ultomiris infusion, call your doctor immediately.

Stopping treatment with Ultomiris 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, dizziness and looking pale
- confusion or a 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 16 weeks after stopping Ultomiris.

Driving or using machines

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

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor as soon as possible if you notice any of the following and they worry you:

- headaches

- sinus or throat infection
- common cold (nasopharyngitis)
- fever
- dizziness
- nausea
- diarrhoea
- vomiting
- stomach pain or discomfort
- joint pain
- pain in arms or legs

The above list includes the more common side effects of Ultomiris.

Tell your doctor or nurse immediately if you experience any side effects during or after your Ultomiris infusion.

When Ultomiris is administered, you may experience infusion reactions such as headache, lower back pain, and infusion-related pain.

Tell your doctor as soon as possible if you notice signs of an infection.

Ultomiris may increase your susceptibility to infection. and sepsis (infection in the blood) especially by a type of bacteria

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

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

- headache with nausea or vomiting
- headache with a fever
- headache with a stiff neck or stiff back
- fever
- fever and rash
- confusion
- muscle aches with flu-like symptoms
- sensitivity to light

These are possible symptoms of meningococcal infection. If you have meningococcal infection you need urgent medical attention.

Always carry your Ultomiris Patient Safety Card which lists the symptoms of meningococcal disease and important contact information.

If you get any side effects, do not stop Ultomiris without first talking to your doctor.

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

Storing Ultomiris

Ultomiris will be stored in refrigerated conditions (2°C to 8°C) in the hospital or pharmacy.

Product description

What Ultomiris looks like

Ultomiris is a translucent, clear to yellowish colour, practically free from particles solution.

Ingredients

Ultomiris contains 100 mg/mL of ravulizumab rch as the active ingredient.

- ravulizumab rch

Other ingredients

- monobasic sodium phosphate
- dibasic sodium phosphate
- polysorbate 80
- L-arginine
- Sucrose

- Water for injections

Manufacturer/Supplier

In Australia Ultomiris is registered by:

Alexion Pharmaceuticals Australasia Pty Ltd

Suite 401, Level 4, Building A.

20 Rodborough Rd. Frenchs Forest.

NSW 2086.

Medical enquiries: 1800 788 189

Registration numbers

Ultomiris concentrated solution for intravenous infusion 300 mg in 3 mL vial: AUST R 330566

Ultomiris concentrated solution for intravenous infusion 1 100 mg in 11 mL vial: AUST R 336710

This leaflet was prepared in March 2021.