Ultomiris®

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 subject to additional monitoring due to approval of an extension of indications. 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. 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 ULTOMIRIS?

ULTOMIRIS contains the active ingredient ravulizumab rch.

For more information, see Section 1. Why am I using ULTOMIRIS? in the full CMI.

2. What should I know before I use ULTOMIRIS?

ULTOMIRIS is a medicine that affects your body's defence system and so can lower the ability of your immune system to fight infections. Using this medicine increases your risk of severe infection and sepsis (infection of the blood). You must be vaccinated against meningococcal infection and be aware of the signs and symptoms of a meningococcal infection. You should seek medical care immediately if you see any signs or symptoms of meningococcal infection. Your doctor will provide you with a 'Patient Safety Card'. You must always carry a 'Patient Safety Card' with you.

Talk to your doctor if you have an infection or have had an allergic reaction to any of the ingredients listed at the end of the CMI.

For more information, see Section 2. What should I know before I use ULTOMIRIS? in the full CMI.

3. What if I am taking other medicines?

Talk to your doctor if you have any other medical conditions or are taking any other medicines. The effect of using ULTOMIRIS on other medicines has not been studied.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use ULTOMIRIS?

- ULTOMIRIS will be given to you directly into the vein (intravenously) by a doctor or nurse. The infusion will take approximately 45 minutes but might take longer according to your body weight.

More instructions can be found in Section 4. How do I use ULTOMIRIS? in the full CMI.

5. What should I know while using ULTOMIRIS?

Things you should do	• Be aware of the signs and symptoms of a meningococcal infection and always carry a 'Patient Safety Card' with you. See Warnings under Section 2. What should I know before I use ULTOMIRIS? • Ensure that your (or your child's) vaccinations are up to date. • If you forget or miss your appointment for an ULTOMIRIS infusion, contact your doctor immediately. • Remind any doctor, dentist, and pharmacist that you visit that you are using ULTOMIRIS.
Things you should not do	• Do not stop using ULTOMIRIS without checking with your doctor.
Looking after your medicine	• ULTOMIRIS will be stored in refrigerated conditions (2°C to 8°C) in the hospital or pharmacy.

For more information, see Section 5. What should I know while using ULTOMIRIS? 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 due to approval of an extension of indications. 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 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 "What I should know before I use ULTOMIRIS" 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 need to be aware of the signs and symptoms of meningococcal infection (see "What I should know before I use ULTOMIRIS" 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 the Emergency Department at your nearest hospital. Show your Patient Safety Card to any doctor or nurse who treats you.

Ultomiris® (uhl-toe-mi-riss)

Active ingredient(s): *ravulizumab rch* [**100 mg per 1mL**]

Consumer Medicine Information (CMI)

This leaflet provides important information about using ULTOMIRIS.

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 ULTOMIRIS.

Where to find information in this leaflet:

1. Why am I using ULTOMIRIS?

ULTOMIRIS contains the active ingredient ravulizumab rch.

ULTOMIRIS belongs to a class of medicines called monoclonal antibodies, that attach to a specific target in the body. Ravulizumab rch has been designed to attach to the C5 complement protein, which is a part of the body's defence system called the 'complement system'.

ULTOMIRIS is used to treat adults and children with a disease called Paroxysmal Nocturnal Haemoglobinuria (PNH).

ULTOMIRIS is also used to treat adults and children with a disease affecting the blood system and kidneys called atypical haemolytic uraemic syndrome (aHUS).

ULTOMIRIS can also be used to treat adult patients with generalised Myasthenia Gravis (gMG), a condition which causes weakness of muscles throughout the body. Patients with gMG can experience challenges with fatigue, drooping eyelids, speech, chewing, movement and breathing, amongst other symptoms.

ULTOMIRIS can also be 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). In NMOSD patients, the eye nerves, brain and spinal cord are attacked and damaged by the immune system working incorrectly, which can lead to loss of sight in one or both eyes, weakness or loss of movement in the legs or arms, painful spasms, loss of feeling, problems with bladder and bowel function and marked difficulties with activities of daily living.

How it works

In patients with PNH, the complement system is overactive and attacks their red blood cells, which can lead to blood clots, low blood cell counts (anaemia), tiredness, difficulty in functioning, pain, abdominal pain, dark urine, shortness of breath, difficulty swallowing and erectile dysfunction. By attaching to and blocking the C5 protein, ULTOMIRIS can stop complement proteins from attacking red blood cells and control symptoms of the disease such as improving anaemia and tiredness.

In patients with aHUS, their complement system attacks vital organs (such as the kidney), blood cells and blood vessels, which can lead to low blood counts (platelets and red blood cells), reduced or lost kidney function, blood

clots, tiredness and difficulty in functioning. ULTOMIRIS can block the body's inflammatory response, and its ability to attack and destroy its own vulnerable blood vessels and control symptoms of the disease including injury to the kidneys.

In gMG patients the immune system (which normally protects the body from infection) attacks itself instead. This autoimmune attack occurs at the connection between nerves and muscles, causing the complement system to damage nerve tissue, resulting in nerves which function poorly.

In patients with NMOSD ULTOMIRIS is presumed to block the body's inflammatory response, and its ability to attack and destroy its own eye nerves, brain and spinal cord, which reduces the risk of relapse or attack of NMOSD. ULTOMIRIS is not intended for acute treatment of NMOSD relapse.

2. What should I know before I use ULTOMIRIS?

Warnings

ULTOMIRIS is a medicine that affects your immune system (your body's defence system). ULTOMIRIS can lower the ability of your immune system to fight infections.

The use of ULTOMIRIS increases your risk of meningococcal infection, a severe infection that can affect the linings of the brain and can spread through the blood and body (sepsis) as well as the risk of other infections (e.g. widespread gonorrhoea).

Due to the importance of rapidly identifying and treating meningococcal infection/sepsis in patients who receive ULTOMIRIS, you will be provided with a 'Patient Safety Card' to carry with you at all times, to ensure you are 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 the Emergency department at your nearest hospital if you have any of the symptoms listed above.

Patients less than 18 years of age must also be vaccinated against *Haemophilus Influenzae* and pneumococcal infections.

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

When ULTOMIRIS is given, you may experience reactions to the infusion (drip) (infusion reaction) such as headache, lower back pain, and infusion-related pain. Some patients may experience allergic or hypersensitivity reactions (including anaphylaxis, a serious allergic reaction which causes difficulty breathing or dizziness).

Should you experience an infusion reaction, your doctor will interrupt the infusion of ULTOMIRIS and institute appropriate measures depending on the severity.

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.

Do not use ULTOMIRIS if:

- you have not been vaccinated against *Neisseria meningitidis*, a bacteria that causes meningococcal infection, or if it has been less than 2 weeks after receiving your meningococcal vaccination and you are not taking antibiotics to reduce the risk of infection.

  You should also be aware that vaccination may not prevent this type of infection. You may need antibiotics to prevent infection. You should discuss with your doctor the use of ongoing preventative antibiotics and if they are required.
- you have unresolved meningococcal infection.
- you are allergic to ravulizumab rch, any other proteins of hamster origin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any infections, or any other medical conditions
- take any medicines for any other condition
- experience any infusion related pain, when ULTOMIRIS is given, you may experience a reaction to the infusion such as a headache or lower back pain
- are on a controlled sodium diet as 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.

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.

ULTOMIRIS has not been studied in pregnant women. Women who may become pregnant should use effective contraception methods during treatment, and for 8 months after stopping treatment.

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

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 for 8 months after stopping treatment.

Elderly

There are no special precautions needed for the treatment of patients aged from 65 years and over, although experience with ULTOMIRIS in elderly patients with PNH and aHUS, or NMOSD in clinical studies is limited.

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 ULTOMIRIS on other medicines has not been studied.

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

4. How do I use ULTOMIRIS?

How much to use

- The doses administered are based on your body weight; your doctor will calculate this.
- ULTOMIRIS will be given to you by infusion (drip) into the vein (intravenously) by a doctor or nurse. The infusion will take approximately 45 minutes but might take longer according to your body weight.
- Your first dose is called the loading dose. Two weeks after receiving your loading dose, you will be given a maintenance dose of ULTOMIRIS. This will be repeated every 8 weeks for patients above 20kg, and every 4 weeks for patients weighing less than 20kg.
- If you were previously receiving another medicine for PNH, aHUS or NMOSD called Soliris®, the loading dose should be given 2 weeks after the last SOLIRIS maintenance infusion or 1 week after the last SOLIRIS induction infusion.

If you forget to use ULTOMIRIS

If you forget or miss your appointment for an ULTOMIRIS infusion, please contact your doctor immediately for advice and see Section 5 Things you should not do for information about the risks of interrupting or stopping your ULTOMIRIS treatment.

If you use too much ULTOMIRIS

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.

5. What should I know while using ULTOMIRIS?

Things you should do

- **Always carry your Patient Safety Card with you and show it to any doctor or nurse that treats you.**
- Ensure that your meningococcal vaccination is up to date.
- You should also be aware that vaccination may not always prevent this type of infection. Your doctor might consider that you need additional measures, such as antibiotics, to prevent infection.
- Ensure that your child's vaccinations are up to date.
- Be aware of the signs and symptoms of a serious infection. See Warnings under Section 2. What should I know before I use ULTOMIRIS?

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

Things you should not do

- Do not stop using this medicine without checking with your doctor.

  Interrupting or stopping treatment with ULTOMIRIS may cause your PNH, aHUS, gMG or NMOSD symptoms to return. Your doctor will discuss the possible side effects with you and explain the risks.

- For PNH, the risks of stopping ULTOMIRIS include an increase in the destruction of your red blood cell which may cause:

  - a large drop in your red blood cell count causing anaemia. Symptoms of anaemia may include tiredness, headaches, dizziness and looking pale
  - dark urine
  - fatigue
  - abdominal pain
  - shortness of breath
  - difficulty swallowing
  - erectile dysfunction (impotence)
  - confusion or a change in how alert you are
  - chest pain or angina
  - blood clots
  - an increase in your serum creatinine level (problems with kidneys).

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.

For aHUS, the risks of stopping ULTOMIRIS include an increase in small blood vessel damage, which may cause:

- a large drop in your platelets (thrombocytopenia)
- a large rise in destruction of your red blood cells
- a large drop in your red blood cell count causing anaemia
- decreased urination (problems with your kidneys)
- an increase in your serum creatinine levels (problems with your kidneys)
- confusion or change in how alert you are

- change in your vision
- chest pain or angina
- shortness of breath
- abdominal pain, diarrhoea
- blood clots.

If you experience any of these symptoms, contact your doctor immediately.

- Your doctor will need to monitor you closely.

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.

Looking after your medicine

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

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
• Sinus or throat infection • Common cold (nasopharyngitis) • Middle ear infection, tonsillitis • Cough • Diarrhoea, constipation • Abdominal pain or discomfort • Loss of appetite • Joint pain (arthralgia) • Back pain • Muscle pain (myalgia) and muscle spasms • Swelling of the hands, ankles or feet • Swollen glands (lymph nodes) • Feeling anxious • Feeling tired (fatigue) • Hair loss or thinning • High blood pressure (hypertension) • Headache • Vomiting • Nausea • Stomach discomfort after meals • Hives, rash, itchy skin (pruritus) • Fever (pyrexia)	**Speak to your doctor if you have any of these less serious side effects and they worry you.**
• Dizziness	

Serious side effects

Serious side effects	What to do
• Meningococcal infection o Headache o Nausea or vomiting o Headache with nausea or vomiting o Headache with a fever o Headache with a stiff neck or stiff back o Fever o Fever and rash o Confusion o Muscle aches with flu-like symptoms o Sensitivity to light o Rash or itchy skin o Feeling tired o Back pain, muscle spasms, aching muscles (not caused by exercise), pain in arms or legs o Looking pale o Dizziness. • Shortness of breath, difficulty in breathing, chest tightness • Pneumonia (severe lung infection) • Urinary tract infections (infections of the bladder) • Allergic reactions (swelling of the face, lips, tongue or other parts of the body, itching or hives).	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of 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 ULTOMIRIS contains

Active ingredient (main ingredient)	ravulizumab rch (100 mg/mL)
Other ingredients (inactive ingredients)	• Monobasic sodium phosphate • Dibasic sodium phosphate • Polysorbate 80 • L-arginine • Sucrose • Water for injections
Potential allergens	Proteins of hamster origin

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

What ULTOMIRIS looks like

ULTOMIRIS 100 mg/mL is a translucent, clear to yellowish colour, practically free from particles solution.

(AUST R 330566 - 300 mg/3mL vial)

(AUST R 336710 - 1100 mg/11mL vial).

Who distributes ULTOMIRIS

ULTOMIRIS is registered by:

Alexion Pharmaceuticals Australasia Pty Ltd

Level 4, 66 Talavera Road, Macquarie Park,

NSW 2113

Medical enquiries: 1800 788 189

This leaflet was prepared in August 2025.