PATIENT INFORMATION LEAFLET

SHEDULING STATUS: S4

ULTOMIRIS 300 mg/3 ml Concentrate for solution for infusion

ULTOMIRIS 1100 mg/11 ml Concentrate for solution for infusion

Ravulizumab

Contains Sugar (Sucrose 50 mg/ml)

Read all of this leaflet carefully before you start taking ULTOMIRIS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ULTOMIRIS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ULTOMIRIS is and what it is used for

Ultomiris is a medicine that contains the active substance ravulizumab and it belongs to a class of medicines called monoclonal antibodies, that attach to a specific target in the body.

ULTOMIRIS is used to treat:

- adults and children one month of age and older with a disease called paroxysmal nocturnal haemoglobinuria (PNH).
- adults and children one month of age and older with a disease affecting the blood system and kidneys called atypical haemolytic uremic syndrome (aHUS).

- adult patients with a certain type of disease affecting the muscles called generalized myasthenia gravis (gMG).
- adult patients with a disease where the body's immune system reacts against its own cells, mainly in the optic nerves that connect the retina of the eye with the brain and in the spinal cord called neuromyelitis optica spectrum disorder (NMOSD).

2. What you need to know before you take ULTOMIRIS

Do not use ULTOMIRIS:

- if you are allergic to ravulizumab or any of the other ingredients of ULTOMIRIS (listed in section 6)
- if you have unresolved meningococcal infection (infection of the lining of the brain and spinal cord caused by a bacteria).
- if you have not been vaccinated against meningococcal infection.

Warnings and precautions

Special care should be taken with ULTOMIRIS:

Meningococcal infection:

The use of ULTOMIRIS increases your risk of meningococcal infection caused by *Neisseria meningitidis*. These are severe infections affecting the linings of the brain and can spread throughout the blood and body (sepsis).

Consult your doctor before you start ULTOMIRIS to be sure that you receive vaccination against *Neisseria meningitidis* at least 2 weeks before beginning therapy. If you cannot be vaccinated 2 weeks beforehand, your doctor will prescribe antibiotics to reduce the risk of infection until 2 weeks after you have been vaccinated.

Meningococcal infection symptoms:

If you experience any of the following symptoms, you should immediately inform your doctor:

- headache with nausea or vomiting
- headache and fever
- headache with a stiff neck or stiff back
- fever
- fever and rash
- confusion

- muscle aches with flu-like symptoms
- eyes sensitive to light

Other Infections

Before starting Ultomiris, inform your doctor if you have any infections.

Infusion reactions

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).

Other medicines and ULTOMIRIS

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health cam provider for advice before taking this medicine.

Women of childbearing potential should use effective pregnancy prevention methods during treatment and up to 8 months after treatment.

Driving and using machines

ULTOMIRIS may cause dizziness. Ensure you do not drive or use machines until you know how ULTOMIRIS affects you.

3. How to use ULTOMIRIS

Do not share medicines prescribed for you with any other person.

At least 2 weeks before you start treatment with ULTOMIRIS, your doctor will give you a vaccine against meningococcal infections if you have not previously had one or if your vaccination is outdated. If you cannot

be vaccinated at least 2 weeks before you start treatment with ULTOMIRIS, your doctor will prescribe antibiotics to reduce the risk of infection until 2 weeks after you have been vaccinated.

You will not be expected to give yourself ULTOMIRIS. It will be given to you by a person who is qualified to do so.

The dose of ULTOMIRIS will be calculated by your doctor, based on 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 and this will be repeated once every 8 weeks or 4 weeks depending on your weight.

ULTOMIRIS is given by infusion (drip) into a vein.

If you are given more ULTOMIRIS than you should

Since a health care provider will administer ULTOMIRIS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use ULTOMIRIS

Since a health care provider will administer ULTOMIRIS, it is unlikely that the dose will be missed.

If you forget an appointment, please contact your doctor immediately for advice.

If you stop taking ULTOMIRIS

Discontinuation of treatment may cause the symptoms of underlying disease.

4. Possible side effects

ULTOMIRIS can have side effects.

Not all side effects reported for ULTOMIRIS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ULTOMIRIS, please consult your health care provider for advice.

The most serious side effect is meningococcal infection

Tell your doctor if you notice any of the following meningococcal infection symptoms:

- headache with nausea or vomiting
- headache and fever
- headache with a stiff neck or stiff back

- fever
- fever and rash
- confusion
- muscle aches with flu-like symptoms
- eyes sensitive to light

Frequent side effects:

- diarrhoea (passing of frequent, watery stools)
- upper respiratory tract infection (infection that affects the nose, throat and airways)
- common cold (Nasopharyngitis)
- headache
- urge to vomit (Nausea)
- abdominal pain
- back pain
- joint pain (Arthralgia)
- increase in body temperature (Pyrexia)
- tiredness (Fatigue)
- hypersensitivity
- dizziness
- vomiting
- indigestion (Dyspepsia)
- raised, itchy rash that appears on the skin (Urticaria/Hives)
- rash pruritus (Itching)
- muscle aches and pain (Myalgia)
- muscle spasms (muscle cramps)
- influenza like illness
- chills
- decreased muscle strength (Asthenia)
- infusion-related reaction

Less frequent side effects:

- infections

- severe, potentially life-threatening allergic reaction (Anaphylactic reaction)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 or report to the applicant at https://contactazmedical.astrazeneca.com/. By reporting side effects, you can help provide more information on the safety of ULTOMIRIS.

5. How to store ULTOMIRIS

Store all medicines out of reach of children.

Store at 2°C – 8°C.

Do not freeze.

After dilution with sodium chloride 9 mg/mL (0.9 %) solution for injection, the medicine should be used immediately, or within 24 hours if refrigerated or within 4 hours at room temperature.

6. Contents of the pack and other information

What ULTOMIRIS contains

The active substance is ravulizumab.

ULTOMIRIS 300 mg/3 ml: each ml contains 100 mg ravulizumab.

ULTOMIRIS 1100 mg/11 ml: each ml contains 100 mg ravulizumab.

The other ingredients are Sodium phosphate, monobasic, Sodium phosphate, dibasic; Polysorbate 80; Larginine; Sucrose; Water for injection

What ULTOMIRIS looks like and contents of the pack

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

ULTOMIRIS is presented as a sterile concentrate in a Type I clear glass vial with a grey butyl rubber stopper and aluminium seal with a polypropylene lavender coloured (3 ml) flip-off cap and aqua coloured (11ml) flip-off cap.

Packs of 1 vial (3 ml or 11 ml) per pack

Holder of certificate of registration

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This leaflet was last revised in

02 July 2025

Registration Numbers

ULTOMIRIS 300 mg : 59/30.1/0014

ULTOMIRIS 1100 mg : 59/30.1/0015