

Please consult the Summary of Product Characteristics and Patient Information Leaflet (PIL) for serplulimab available at: <https://www.ema.europa.eu/en/medicines/human/EPAR/hetronifly/hetronifly> or contact Accord Healthcare by calling 0044 1271 385 257 or by emailing: medinfo@accord-healthcare.com for more information.

IMPORTANT INFORMATION FOR HEALTH CARE PROVIDERS

This patient is being treated with Hetronifly (serplulimab), which can cause infusion-related reactions as well as immune-mediated adverse reactions that affect the lungs, liver, heart, intestines, hormone glands, kidneys, pancreas and other organs. Early diagnosis and appropriate management are essential to minimise any consequences of immune-mediated adverse reactions.

For suspected immune-mediated adverse reactions, adequate evaluation should be performed to confirm aetiology or exclude other causes. Specific guidelines for managing immune-mediated adverse reactions and infusion-related reactions are available in the Summary of Product Characteristics for serplulimab available at <https://www.ema.europa.eu/en/medicines/human/EPAR/hetronifly/hetronifly> or contact Accord Healthcare by calling 0044 1271 385 257 or by emailing: medinfo@accord-healthcare.com or the local distributor EJ Busuttil Ltd on 00356 21447184 or safety@ejbusuttil.com for more information.

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Assess patients for signs and symptoms of pneumonitis, hepatitis, myocarditis, colitis, endocrinopathies (including hypothyroidism, hyperthyroidism, thyroiditis, adrenal gland disorders, pituitary disorders, diabetes mellitus/hyperglycaemia), pancreatitis, nephritis and renal dysfunction, uveitis, and other immune-mediated adverse reactions, including myasthenia gravis and myasthenic syndrome, reported in patients receiving serplulimab.

Reporting Side Effects

If you get any side effects, talk to your doctor, pharmacist or nurse. You can report side effects directly via:
ADR Reporting Website:
www.medicinesauthority.gov.mt/adrportal

By reporting side effects, you can help provide more information on the safety of this medicine. Side effects should also be reported to Accord Healthcare by calling 0044 1271 385 257 or by emailing: safety.eu@lambda-cro.com

Local Distributor: EJ Busuttil Ltd
Tel: 00356 21447184
safety@ejbusuttil.com

Serplulimab Patient Card Version 2 Date of Preparation: April 2026 Date of Malta Medicines Authority July 2026

BBBC4907 6

IMPORTANT CONTACT INFORMATION

Name of Specialist _____

Phone _____

After-hours Phone _____

My Name _____

My Phone _____

Emergency Contact (Name) _____

Emergency Contact (Phone) _____

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HETRONIFLY® ▼ (serplulimab) Patient Card

IMPORTANT

This card contains important safety information on your serplulimab treatment.

Keep this card with you at all times during your treatment and at least 3 months after completing your treatment with serplulimab. Always show it to any healthcare professional involved in your treatment.

Important Safety Information to minimise the risk of immune-mediated side effects.

- Contact your specialist right away if you develop any signs or symptoms described in this card.
- For further information, consult the Patient Information Leaflet or contact Accord Healthcare by calling 0044 1271 385 257 or by emailing: medinfo@accord-healthcare.com

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

Speak with your doctor immediately if you develop any signs or symptoms, which may include those listed below:

Lungs

- Shortness of breath or chest pain
- New or worsening of existing cough

Liver

- Yellowing of skin and whites of your eyes (jaundice)
- Nausea or vomiting (Severe)
- Pain on the right side of your stomach area (abdomen)
- Drowsiness
- Dark urine (tea coloured)
- Bleeding or bruising more easily than normal
- Feeling less hungry
- Tiredness
- Abnormal liver function tests

Heart

- Shortness of breath
- Chest pain and chest tightness
- Irregular heartbeat
- Dizziness or fainting
- Fever
- Flu-like symptoms

Hormone glands

- Extreme tiredness
- Fast heart rate
- Increased sweating

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- Changes in mood or behaviour, such as irritability or forgetfulness
- Very low blood pressure (fainting, dizziness, fatigue, and nausea)
- Constipation
- Abdominal pain
- Nausea and vomiting
- Hair loss
- Feeling cold
- Weight gain or weight loss
- Headaches that will not go away or unusual headaches

Diabetes / diabetic ketoacidosis

- High blood sugar
- Feeling more hungry or thirsty than usual
- Passing urine more often than usual
- Fast and deep breathing
- Confusion
- Sweet smell to your breath
- Fruity smell to your breath
- Sweet or metallic taste in your mouth
- Different odour to your urine or sweat
- Weight Loss
- Feeling tired
- Having difficulty thinking clearly
- Feeling sick or being sick
- Stomach pain

Bowel and stomach

- Diarrhoea (loose stools)
- More bowel movements than usual
- Stools that are black, tarry or sticky with blood or mucus
- Severe stomach pain or tenderness

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Kidneys

- Inflammation of the kidneys: symptoms may include a decrease in the amount of urine you pass
- Abnormal kidney function tests
- Blood in your urine
- Swelling in your ankles

Eye

- Inflammation of the eyes, which may include changes in eyesight
- Eye pain
- Eye redness
- Sensitivity to light
- Blurred or cloudy vision
- Small shapes moving across your field of vision (floaters)
- Loss of peripheral vision (the ability to see objects at the side of your field of vision)

Pancreas

- Abdominal pain
- Nausea
- Vomiting

Muscle

- Muscle pain
- Muscle weakness or rapid fatigue

Skin

- Rash or itching
- Skin blistering
- Ulcers in the mouth or on other moist surfaces

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Nervous system

- Headache or stiff neck
- Fever
- Feeling tired or weak
- Chills
- Vomiting
- Confusion
- Memory problems or feeling sleepy
- Fits (seizures)
- Seeing or hearing things that are not really there (hallucinations)

Infusion-related reactions

- Shortness of breath or wheezing
- Chills or shaking
- Itching or rash or skin wheals
- Flushing
- Dizziness or fever
- Low blood pressure (dizziness, fatigue, nausea)
- Fever
- Back pain
- Abdominal pain

IMPORTANT

- Do not attempt to diagnose or treat side effects by yourself.
- Carry this Patient Card with you at all times, especially when you travel, whenever you go to the Emergency Room, or when you must see another doctor, nurse or pharmacist.
- Be sure to notify any healthcare professional you see that you are being treated with serplulimab and show them this card.

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Serplulimab 10mg/ml Concentrate for Solution for Infusion RMM Patient Alert Card - Ireland

Item number: BBBC4907

Originator: NM
Origination Date: 20/02/2026
Revision Date: 27/04/2026
Revised By: NM

Dimensions: 85x216mm
Min Body Text Size: 6.5pts
Supplier: N/A

CRF number: N/A

Digital signature

Proof Round

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Technical Date sent: N/A
Approval Date received:

Colours

1. Black
2. PMS 158
- 3.
- 4.
- 5.
- 6.

Non Printing Colours

1. Profile
- 2.
- 3.
- 4.
- 5.
- 6.

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EMENA Artwork Team

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