ASPAVELI®
(pegcetacoplan)

A GUIDE TO ASPAVELI®
(pegcetacoplan) for patients and caregivers

This guide contains important information and safety considerations for pegcetacoplan, including the risk of serious infections (including meningitis) and guidance on self administration.

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store . By reporting side effects, you can help provide more information on the safety of this medicine. Side effects should also be reported to Swedish Orphan Biovitrum Ltd by email at medical.info.uk@sobi.com or by calling +44 (0) 800 111 4754.

This guide must be used in combination with the pegcetacoplan Patient Information Leaflet (PIL) which is provided separately. The PIL is also available at **www.medicines.org.uk/emc**.

The information provided in this leaflet does not take the place of professional medical advice. Always follow your doctor, nurse or pharmacist's instructions and talk with them about any questions or problems you have regarding your health and treatment.

This RMM material fulfils the conditions of the marketing authorisation and has been approved by the MHRA.
Date of MHRA Approval: August 2026

NP-49919 August 2026

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Introduction

This booklet has been given to you because you, or someone in your care, has been prescribed pegcetacoplan. This guide covers what pegcetacoplan is, as well as important safety considerations for patients and their carers and information on where to access the self-administration guide.

Injecting yourself or someone in your care may seem difficult when you first begin, but there are tips that might make it easier to incorporate the administration into your daily routine. Read this booklet and make sure you understand the information. If you have any questions speak to your doctor, nurse or pharmacist.

Your doctor or nurse will provide you with a pegcetacoplan Patient Card. Please work with your doctor or nurse to fill out the card and keep it with you **at all times** to quickly reference your treatment, doctor's phone number, and important safety information.

Your doctor or nurse can answer any specific questions about the diagnosis and treatment management.

What is ASPAVELI?

ASPAVELI is a medicine that is used to treat adult patients with a disease called paroxysmal nocturnal haemoglobinuria (PNH), and to treat adults and adolescents aged 12 – 17 years with diseases called Complement 3 glomerulopathy (C3G) and primary Immune-complex membranoproliferative glomerulonephritis (IC-MPGN). The treatment is given by infusion under the skin.

It contains the active substance pegcetacoplan. Pegcetacoplan has been designed to attach to the C3 complement protein, which is a part of the body's defences against infection called the 'complement system'. In PNH patients, pegcetacoplan prevents your body's immune system from destroying your red blood cells. In C3G and primary IC-MPGN patients, pegcetacoplan prevents C3 fragments from being deposited in the kidneys and causing damage.

Patient Card:
You will receive a pegcetacoplan Patient Card from your doctor.

- Carry this card at all times during treatment with pegcetacoplan and for 12 weeks after your last dose.
- Show this card to any doctor, nurse or pharmacist who treats you. This will help them to diagnose and treat you correctly.
- Seek emergency medical help for any symptoms of serious bacterial infections even if you do not have your card on you.

Important information to know before starting treatment with pegcetacoplan

Risk of serious infections

The use of this medicine increases your risk of infections, including those caused by the bacteria *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae*. These are severe bacterial infections affecting your nose, throat and lungs or the linings of the brain and can spread throughout the blood and body. Serious bacterial infections may quickly become life-threatening and cause death if not recognised and treated early.

Call your doctor or nurse or seek emergency medical help right away if you have any of these signs and symptoms of a serious infection:

- Headache and a fever
- Fever and a rash
- Fever with or without shivers or chills
- Shortness of breath
- High heart rate
- Clammy skin
- Headache with a stiff neck or stiff back
- Headache with nausea (feeling sick) or vomiting
- Eyes sensitive to light
- Muscle aches with flu-like symptoms
- Confusion
- Extreme pain or discomfort

Risk of allergic reactions

Allergic reactions may occur in some patients receiving treatment with pegcetacoplan.

Immediately stop pegcetacoplan infusion if you develop any of these signs and symptoms of an allergic reaction and seek immediate medical attention:

- Difficulty breathing
- Chest pain or chest tightness
- Feeling dizzy/faint
- Severe itching of the skin or raised lumps on the skin
- Swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing or collapse

Prophylactic vaccinations or antibiotic treatment

Vaccines against bacteria lower the risk of getting serious infections. However, vaccines do not prevent all serious infections.

Your doctor will ensure that you receive vaccination against the bacteria *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* according to applicable local guidelines if you have not had these vaccines in the past.

If you have had these vaccines in the past, you might still need additional vaccinations before starting treatment with pegcetacoplan. Your doctor will advise if you need additional vaccinations.

You should receive these vaccinations at least 2 weeks before beginning pegcetacoplan therapy.

If you cannot be vaccinated 2 weeks before beginning pegcetacoplan therapy, your doctor will prescribe antibiotics (medications to treat bacterial infections) to reduce the risk of infection, which should continue for 2 weeks after you have been vaccinated. Pegcetacoplan will only be supplied if your doctor or pharmacist submits proof that you are receiving the required vaccinations or antibiotics. Your doctor or pharmacist will receive annual reminders in case you need revaccination.

It is important that your vaccinations are up to date, so speak with your doctor or nurse about this. You should also be aware that vaccines will reduce the risk of serious infections, but do not prevent all serious infections.

Important information...continued

Risk of intravascular haemolysis after drug discontinuation (PNH patients only)

- Do not stop treatment with pegcetacoplan without discussing this beforehand with your doctor or nurse.
- It is very important to make sure that you do not miss or postpone any scheduled treatments. If you stop taking the medicine suddenly, you may be at risk of making your symptoms worse.
- If pegcetacoplan treatment is stopped completely, postponed, or if treatments are missed, there is a risk that one of the serious features of PNH, haemolysis, could occur. Haemolysis is when red blood cells, which carry oxygen through your body, break apart. Haemolysis is connected to various symptoms of PNH, such as:

  - Tiredness (fatigue)
  - Dark urine (haemoglobinuria)
  - Tummy (abdominal) pain
  - Breathlessness
  - Formation of blood clots (thrombosis)
  - Difficulty in swallowing
  - Erectile dysfunction

- Seek immediate medical attention if you notice any signs or symptoms of haemolysis.

Recommendations for contraception for women of childbearing potential

The effects of pegcetacoplan on an unborn child are not known. The use of effective contraception is recommended during treatment and up to 8 weeks after treatment by women of childbearing age. Ask your doctor, nurse, or pharmacist for advice before taking pegcetacoplan.

Set up for self-administration

Pegcetacoplan is given as a subcutaneous (under the skin) infusion using an infusion pump or an on-body delivery system. Your doctor or nurse will support you with your initial infusions. If your doctor or nurse thinks that you can self-administer, you will receive full training in subcutaneous infusion, after which you will be able to administer your dose yourself at home as agreed with your doctor.

Pegcetacoplan comes in a glass vial, which needs to be kept in the refrigerator (2°C to 8°C [35.6°F to 46.4°F]), in the original carton, to protect the liquid from light. One vial contains the dose for one infusion.

You can find descriptions on how to self-administer:

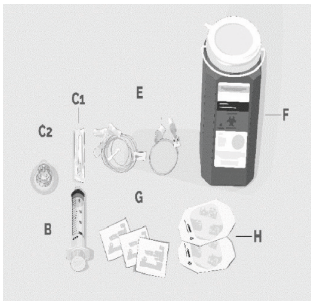
- In the pegcetacoplan Patient Information Leaflet
- In the infusion pump manufacturer's instructions
- In the on-body delivery system manufacturer's instructions
- In the video links below.

Description of the modalities used for self-infusion:

For your infusion you will need:

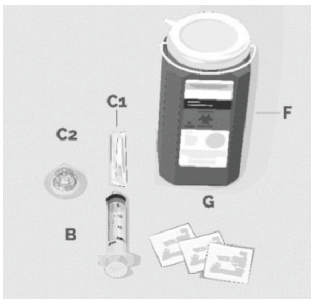
1. When using an infusion pump:

   A. Syringe system infusion pump and manufacturer´s instructions (not shown)
   B. Compatible syringe
   C1. Transfer needle OR
   C2. Needleless transfer device to draw up product from the vial
   D. Infusion set (not shown; varies according to device manufacturer's instructions)
   E. Infusion tubing and Y-connector (if required)
   F. Sharps container
   G. Alcohol wipes
   H. Gauze and tape, or transparent dressing



2. When using an on-body delivery system:

   A. On-body delivery system and manufacturer´s instructions (not shown)
   B. Compatible syringe
   C1. Transfer needle OR
   C2. Needleless transfer device to draw up product from the vial
   F. Sharps container
   G. Alcohol wipes



Instructions on how to view the pegcetacoplan self-administration video on any internet-connected device

Please click on the link below or type the web address into your internet browser. You can also use the QR code below to access the video.

Infusion pump:

www.aspaveli-instructions.com/uk

On-body delivery system:

www.aspaveli-instructions.com/uk

Reporting side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Patient Information Leaflet (PIL) in particular serious infections with encapsulated bacteria, severe hypersensitivity reactions, or haemolysis after drug discontinuation.

You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

Side effects should also be reported to Swedish Orphan Biovitrum Ltd by email at medical.info.uk@sobi.com or by calling +44 (0) 800 111 4754.

Taking part in a PNH Post Authorisation Safety Study (PASS)

A Post Authorisation Safety Study (PASS) aims to monitor a medicine's long-term safety after it is authorised.

The PNH PASS will use safety data collected in a separate Sobi-sponsored observational study called Sobi.PEGCET-304.

By agreeing to participate, your physician will enrol you in Sobi.PEGCET-304, which will monitor the real-world effectiveness of pegcetacoplan in patients with PNH. This observational study is also collecting data on safety and patient- and clinician-reported outcomes.

The safety data from Sobi.PEGCET-304 will be extracted and transferred to the PASS (PEGCET-301).

Before enrolment in Sobi.PEGCET-304, you will receive detailed information about the study and will be asked to sign a consent form to participate. Your participation is entirely voluntary and information that would allow direct or indirect identification of you will be removed. In addition, you can withdraw your permission at any time.

Confidentiality and personal data protection

All the information you provide will be managed in accordance with Sobi's Data Privacy Policy and in compliance with the purposes for which it is provided. For complete information on how personal data is protected at Sobi, please see our policy available here: https://www.sobi.com/uk/en/privacy-policy. If you do not agree to these uses of your information, please contact us using the contact information provided on the web page.

More information

If you have any questions about your health or pegcetacoplan talk to your doctor, nurse or pharmacist.

Sobi contact information:

Email: medical.info.uk@sobi.com

Phone: +44 (0) 800 111 4754

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