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.

▼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. See page 8 for how to report side effects.

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.

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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.

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.

Important information to know before starting treatment with pegcetacoplan

Risk of serious infections

The use of pegcetacoplan targets the complement system, which is part of the body's defences against infection. As such, the use of this medicine increases your risk of infections, including those caused by the so-called 'encapsulated bacteria', such as *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* 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.

These vaccinations should be given 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, 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 vaccination reminders and will contact you 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 destruction of red blood cells (haemolysis) after drug discontinuation

- 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 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.

Instructions on self-administration of pegcetacoplan

Pegcetacoplan is given as a subcutaneous (under the skin) infusion with an infusion pump. 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 twice-weekly dose yourself at home.

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 a detailed description on how to self-administer in the pegcetacoplan Patient Information Leaflet, or in the video link below.

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

Please type the below web address into your internet browser to view the pegcetacoplan self-administration video. You can also use the QR code below to access the video.

www.aspaveli-instructions.com/uk

Reporting side effects

Reporting side effects of your treatment is important as it allows collection of more information about the safety of pegcetacoplan. If you experience any side effects (this also includes any possible side effects not listed in the Patient Information Leaflet), in particular serious infections with encapsulated bacteria, severe hypersensitivity reactions, or haemolysis after drug discontinuation, inform your doctor, nurse or pharmacist.

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via:

• the Yellow Card website www.mhra.gov.uk/yellowcard

• the free Yellow Card app available from the Apple App Store or Google Play Store

Alternatively you can report a suspected side effect to the Yellow Card scheme by calling +44 (0) 800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

Taking part in a study to further investigate the safety of pegcetacoplan

A Post-Authorisation Safety Study (PASS) is an ongoing study that is carried out after a medicine has been authorised, to obtain further information on a medicine's long-term safety. The ongoing safety study for pegcetacoplan will be initiated by the end of 2022.

Your doctor or nurse will ask if you are willing to participate in the pegcetacoplan ongoing safety study. By agreeing to participate, you will take part in a Sobi-sponsored ongoing safety study, which will monitor the long-term safety of pegcetacoplan in adult patients with PNH.

If you agree to participate in the ongoing safety study, your doctor or nurse will register you and collect some of your medical information such as diagnosis, treatment, and medical history. 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 to be involved with the study at any time.

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://sobi-uk.co.uk/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:

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