ASPAVELI®▼
(pegcetacoplan)

IMPORTANT INFORMATION
to communicate to patients/ caregivers prior to prescribing ASPAVELI®▼ (pegcetacoplan)

Guide for Healthcare Professionals

This guide fulfils the conditions of the pegcetacoplan marketing authorisation and has been approved by the HPRA (Health Products Regulatory Authority). Please communicate the information outlined in this booklet to the patient/ caregiver to ensure early detection, careful monitoring, and prompt management of important safety concerns when prescribing pegcetacoplan.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See page 8 for details on how to report adverse reactions.

This guide must be used in combination with the pegcetacoplan Summary of Product Characteristics (SmPC), which is provided separately. The SmPC is also available at https://www.medicines.ie/medicines/aspaveli-1080-mg-solution-for-infusion-35187/spc.

Please see the SmPC for pegcetacoplan for more detailed safety information, in particular on serious infections caused by encapsulated bacteria.

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Introduction

Why you have received this material

This educational material is intended to enhance healthcare professionals' awareness around the risk of serious infection with encapsulated bacteria, serious hypersensitivity reactions, and intravascular haemolysis (IVH) after drug discontinuation and postponement of administration.

Important information

In patients with a known history of vaccination, it should be ensured that patients have received vaccines against encapsulated bacteria including *Streptococcus pneumoniae*, *Neisseria meningitidis* types A, C, W, Y, and B, and *Haemophilus influenzae* type B within 2 years prior to starting pegcetacoplan. Pegcetacoplan can only be dispensed after written confirmation that the patient has received vaccinations within the past 2 years against the encapsulated bacteria outlined above, according to applicable local guidelines or prophylactic treatment with appropriate antibiotics until 2 weeks after the patient is vaccinated (controlled distribution, CD) and prescribers need to complete a Vaccination and/or Prophylactic Antibiotic Confirmation Form.
Orders will not be processed for patients unless a correctly completed Vaccination and/or Prophylactic Antibiotic Confirmation Form is received.

In order to contact the controlled distribution coordinator, please send an email to TCP Homecare: pharmacy@tcp.ie or phone: 00 353 1 4291823.

This guide must be used in combination with the pegcetacoplan Summary of Product Characteristics, which is provided separately. You will also receive a Vaccination and/or Prophylactic Antibiotic Confirmation Form which must be completed and signed for each patient before pegcetacoplan can be dispensed. The pegcetacoplan risk management plan also contains the following materials which must be provided to patients:

- Pegcetacoplan Patient Information Leaflet.
- Pegcetacoplan Patient Card.
- A guide to pegcetacoplan for patients and carergivers.

You must ensure that you read these materials and educate your patients on the content ahead of prescribing pegcetacoplan.

Safety considerations

Risk of serious infection due to encapsulated bacteria

- Use of pegcetacoplan may predispose individuals to serious infections, especially those caused by encapsulated bacteria, such as *Streptococcus pneumoniae*, *Neisseria meningitidis* types A, C, W, Y and B, and *Haemophilus influenzae* type B.
- Assess patients for early signs and symptoms of serious infection (see page 6) and treat patients immediately if an infection is suspected.

Prophylactic vaccinations or antibiotic treatment

- To reduce the risk of infection, all patients must be vaccinated against *Streptococcus pneumoniae*, *Neisseria meningitidis* types A, C, W, Y and B, and *Haemophilus influenzae* type B within 2 years prior to starting Aspaveli or according to applicable local vaccination guidelines.
- Patients must be vaccinated against encapsulated bacteria **at least 2 weeks prior** to administering the first dose of pegcetacoplan, unless the risk of delaying therapy outweighs the risk of developing an infection.
- If immediate therapy with pegcetacoplan is required, the required vaccines should be administered as soon as possible, and the patient should be treated with appropriate broad-spectrum antibiotics, in accordance with current national recommendations **until 2 weeks after vaccination**.
- Vaccination reduces, but does not eliminate, the risk of serious infections. Monitor patients for early signs of serious infections and evaluate if an infection is suspected. Promptly treat any known infections.
- You will receive a Vaccination and/or Prophylactic Antibiotic Confirmation Form as part of the risk management plan for pegcetacoplan which must be completed and signed for each patient to confirm that they have received the appropriate vaccinations or antibiotic treatment as outlined above.
- You will receive annual reminders to review the status of relevant vaccinations and revaccinations for patients in accordance with applicable local guidelines.

Risk of intravascular haemolysis (IVH) after discontinuation and postponement of administration of pegcetacoplan

- After discontinuing treatment with pegcetacoplan, closely monitor patients for signs and symptoms of intravascular haemolysis, identified by elevated lactate dehydrogenase (LDH) levels along with a sudden decrease in PNH clone size or haemoglobin, or reappearance of symptoms such as fatigue, haemoglobinuria, abdominal pain, dyspnoea, major adverse vascular events (including thrombosis), dysphagia, or erectile dysfunction.
- If discontinuation of this medicinal product is necessary, alternative therapy should be considered.
- Monitor any patient who discontinues pegcetacoplan for at least 8 weeks to detect haemolysis and/or other reactions. In addition, slow weaning should be considered. If serious haemolysis occurs after discontinuation, consider the following procedures/ treatments: blood transfusion (packed RBCs), exchange transfusion, anticoagulation, and corticosteroids.
- Inform patients who discontinue treatment with pegcetacoplan to keep the pegcetacoplan Patient Card with them for 8 weeks after their last dose, because the increased risk of serious infection persists for several weeks following treatment discontinuation.

Risk of potential long-term effects of Polyethylene Glycol (PEG) accumulation

- Pegcetacoplan is a PEGylated medicinal product.
- The potential long-term effects with use of PEGylated medicinal products and the accumulation of PEG in the kidneys, the choroid plexus of the brain, and other organs are unknown.
- Regular laboratory testing of renal function is recommended.

What patients and caregivers need to know

Risk of serious infections (*N. meningitidis*, *S. pneumoniae*, and *H. influenzae*)

Once you have discussed pegcetacoplan with the patient or caregiver and agreed that it should be prescribed, ensure that you inform the patient or caregiver of the following important information:

- The use of pegcetacoplan increases their risk of serious infections, including those caused by the bacteria *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae*. If the patient experiences symptoms of serious bacterial infection, they should seek emergency medical treatment and show their pegcetacoplan Patient Card to the treating healthcare professional.
- Signs and symptoms of the serious bacterial infections mentioned above:

- 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 or vomiting
- Eyes sensitive to light
- Muscle aches with flu-like symptoms
- Confusion
- Extreme pain or discomfort

- Patients will require vaccination against encapsulated bacteria or the use of antibiotic prophylaxis until 2 weeks after they are vaccinated. Vaccinations should be kept up to date while patients are receiving treatment with pegcetacoplan in accordance with current national recommendations. You will receive annual reminders to review the status of relevant vaccinations and revaccinations.

Hypersensitivity reactions

- Allergic reactions may occur in some patients receiving treatment with pegcetacoplan. They should discontinue pegcetacoplan infusion and seek emergency medical help immediately, if they have any signs and symptoms of an allergic reaction.
- Signs and symptoms of severe allergic reactions:

- 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

Risk of intravascular haemolysis

- There is a risk of intravascular haemolysis after discontinuation and postponement of administration of pegcetacoplan. Patients should inform their doctor or nurse immediately if they notice any signs or symptoms of haemolysis.

Materials and information to be given to patients/caregivers

- Patients will receive materials to support their treatment with pegcetacoplan, including:
  - Pegcetacoplan Patient Information Leaflet.
  - Pegcetacoplan Patient Card.
  - A guide to pegcetacoplan for patients and carergivers.
- Inform patients of the need to carry the pegcetacoplan Patient Card with them and to tell any doctor, nurse, or pharmacist that they see that they are receiving treatment with pegcetacoplan.
- Possibility to take part in the Sobi-sponsored Post Authorisation Safety Study (PASS).

Reporting adverse drug reactions

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions including those of serious infections with encapsulated bacteria, severe hypersensitivity reactions and intravascular haemolysis after discontinuation of the medicinal product.

Reporting any suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse drug reactions via HPRA Pharmacovigilance, website: www.hpra.ie.

Adverse events can also be reported to Swedish Orphan Biovitrum Ltd at medical.info.uk@sobi.com or by calling +44 (0) 800 111 4754.

Taking part in a Post Authorisation Safety Study (PASS)

Sobi will conduct a Post Authorisation Safety Study (PASS) to monitor the long-term safety of pegcetacoplan in patients with PNH and evaluate the occurrence of serious infections (Study Sobi.PEGCET-301).

Information collected from Sobi.PEGCET-301 will also be used to evaluate the effectiveness of additional risk minimisation measures, such as the system for controlled distribution, and guides for healthcare professionals and patients that aim to reduce and mitigate the risk of serious infections with encapsulated bacteria.

Sobi.PEGCET-301 will use safety data extracted from a separate Sobi-sponsored study data base, Sobi.PEGCET-304.

Sobi.PEGCET-304 is an observational study designed to describe the real-world effectiveness of pegcetacoplan in patients with PNH. Sobi.PEGCET-304 is currently ongoing and is collecting both retrospective and prospective data with the main part being prospective, collecting data on effectiveness, safety (all adverse events), patient- and clinician-reported outcomes and health care resource use (ClinicalTrials.gov ID: NCT05776472).

Inform patients about Sobi.PEGCET-304 and how they can participate. For further information, please contact your local Sobi team.

Confidentiality and 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.

Further information

For more information about pegcetacoplan contact:

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