ASPAVELI® ▼ (pegcetacoplan) 1080 mg solution for infusion

PRESCRIBING INFORMATION (PI) FOR UNITED KINGDOM

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Each 20 mL vial contains 1080 mg of pegcetacoplan. Each mL contains 54 mg of pegcetacoplan.

Indications: ASPAVELI® is indicated as monotherapy in the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who have haemolytic anaemia and for the treatment of adult and adolescent patients aged 12 to 17 years with C3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN) in combination with a renin-angiotensin system (RAS) inhibitor, unless RAS inhibitor treatment is not tolerated or contraindicated..

Dosage and administration: Therapy should be initiated under the supervision of a healthcare professional experienced in the management of patients with haematological or renal disorders. Self-administration and home infusion should be considered for patients who have tolerated treatment well in experienced treatment centres.

PNH: Adult Patients with PNH: Pegcetacoplan is administered twice weekly as a 1080 mg subcutaneous infusion with a commercially available syringe system infusion pump or on-body delivery system, that can deliver doses up to 20 mL. The twice weekly dose should be administered on Day 1 and Day 4 of each treatment week. Switching to ASPAVELI® from a C5 inhibitor: For the first 4 weeks, administer as twice weekly subcutaneous doses of 1080 mg in addition to the patient's current dose of C5 inhibitor treatment to minimise the risk of haemolysis with abrupt treatment discontinuation. After 4 weeks, discontinue C5 inhibitor before continuing monotherapy with ASPAVELI®. Switches from complement inhibitors other than eculizumab have not been studied. Discontinuing other complement inhibitors before reaching steady-state of pegcetacoplan should be done with caution. Dose adjustment in PNH: The dosing regimen may be changed to 1080 mg every third day if the patient has a lactate dehydrogenase (LDH) level greater than 2 × upper limit of normal. In the event of a dose increase, LDH should be monitored twice weekly for at least 4 weeks.

C3G: Pegcetacoplan is administered twice weekly as a subcutaneous infusion with a commercially available syringe system infusion pump or on-body delivery system, that can deliver doses up to 20 mL. The twice weekly dose should be administered on Day 1 and Day 4 of each treatment week. C3G and primary IC-MPGN are chronic diseases. Discontinuation of this medicinal product is not recommended unless clinically indicated. Adult patients with C3G or primary IC-MPGN: Pegcetacoplan is administered twice weekly as a 1 080 mg subcutaneous infusion. Adolescent patients with C3G or primary IC-MPGN: For adolescent patients, the dosing regimen is based on the patient´s body weight. For further information regarding weight based dosing, consult section 4.2 of the SmPC.

Missed Dose: If a dose of pegcetacoplan for treatment of PNH, C3G or primary IC-MPGN is missed, it should be administered as soon as possible, then the regular schedule should be resumed even if this results in an interval of less than 3 days between the replacement dose and the subsequent dose Patients with post-transplant recurrent C3G or primary IC-MPGN: Diagnosis of post-transplant recurrent C3G or primary IC-MPGN should be made based on a renal allograft biopsy. C3G or primary IC-MPGN recurrence may be detected in a routine post-transplant biopsy; otherwise, a biopsy should be performed when clinical signs indicate recurrent disease. See section 5.1 of the SmPC for further information regarding starting treatment before the onset of clinical signs such as estimated glomerular filtration rate (eGFR) decrease or urine to protein-to-creatine ratio (uPCR) increase. Elderly population: Although there were no apparent age related differences observed in clinical studies, the number of patients aged 65 and over is not sufficient to determine whether they respond differently from younger patients. There is no evidence indicating any special precautions are required for treating an elderly population. Renal impairment: Severe renal impairment (creatinine clearance <30 mL/min) had no effect on the pharmacokinetics (PK) of pegcetacoplan; therefore, pegcetacoplan dose adjustment in patients with renal impairment is not necessary. There are no data available for the use of pegcetacoplan in patients with end stage renal disease (ESRD) requiring dialysis. Hepatic impairment: The safety and efficacy of pegcetacoplan have not been studied in patients with hepatic impairment; however, no dose adjustment is recommended, as hepatic impairment is not expected to impact clearance of pegcetacoplan. Paediatric population: The safety and efficacy of ASPAVELI® in children with PNH aged 0 to <18 years have not yet been established. No data are available. The safety and efficacy of ASPAVELI® in children with C3G or primary IC-MPGN aged below 12 years have not been established. No data are available. This medicinal product should not be used in children <12 years of age, as non clinical safety data are not available for this age group. Method of administration: When using a syringe system infusion pump, it should be infused in the abdomen, thighs, hips, or upper arms. Infusion sites should be at least 7.5 cm apart from each other. The typical infusion time is approximately 30 minutes (if using two sites) or approximately 60 minutes (if using one site). When using an on-body delivery system, it should be infused at a site on the abdomen. The infusion site should be rotated between administrations following the device manufacturer´s instructions. The infusion time varies by patient and typically ranges from 30 to 60 minutes. Administration should be completed within 2 hours after preparing the syringe. See SmPC for instructions on the preparation and infusion of the medicinal product.

Contraindications: Hypersensitivity to pegcetacoplan or to any of the excipients listed in section 6.1 of the SmPC. Patients with unresolved infection caused by encapsulated bacteria (e.g., *Neisseria meningitidis*, *Streptococcus*

pneumoniae, and *Haemophilus influenzae*) or not currently vaccinated against these bacteria, unless they receive prophylactic treatment with appropriate antibiotics until 2 weeks after vaccination.

Special warnings and precautions for use: Serious infections caused by encapsulated bacteria: Pegcetacoplan may predispose individuals to serious infections caused by encapsulated bacteria. All patients must be vaccinated against these bacteria according to applicable local guidelines at least 2 weeks prior to receiving pegcetacoplan unless the risk of delaying therapy outweighs the risk of developing an infection. Known history of vaccination: Before receiving treatment, 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. Unknown history of vaccination: The required vaccines should be administered at least 2 weeks prior to receiving the first dose. If immediate therapy is indicated, the required vaccines should be administered as soon as possible, and the patient treated with appropriate antibiotics until 2 weeks after vaccination. Monitoring for serious infections: Vaccination may not be sufficient to prevent serious infection. Monitor for early signs of infections caused by encapsulated bacteria, evaluate patient immediately if infection is suspected, and treat with appropriate antibiotics if necessary. Hypersensitivity: If a severe hypersensitivity reaction (including anaphylaxis) occurs, pegcetacoplan must be discontinued immediately, and appropriate treatment instituted. Injection site reactions: Patients should be trained appropriately in proper injection technique. PNH laboratory monitoring: Patients with PNH should be monitored regularly for signs and symptoms of haemolysis, including measuring LDH levels, and may require dose adjustment within the recommended dosing schedule in section 4.2 of the SmPC. Laboratory tests: There may be interference between silica reagents in coagulation panels and pegcetacoplan that results in artificially prolonged activated partial thromboplastin time; the use of silica reagents in coagulation panels should be avoided. Treatment discontinuation for PNH: Patients should be closely monitored for signs and symptoms of serious intravascular haemolysis. If discontinuation is necessary, alternate therapy should be considered. If serious haemolysis occurs after discontinuation consider; blood transfusion (packed RBCs), exchange transfusion, anticoagulation, and corticosteroids. Monitor patients closely for at least 8 weeks from the last dose to allow for medicinal product washout to detect serious haemolysis and other reactions. In addition, slow weaning should be considered. Polyethylene glycol (PEG) accumulation: ASPAVELI® is a PEGylated medicinal product. Regular laboratory testing of renal function is recommended. Educational materials: All physicians who intend to prescribe ASPAVELI® must ensure they have received and are familiar with the physician educational material. Physicians must explain and discuss the benefits and risks of ASPAVELI® therapy with the patient and provide them with the patient information pack and the patient card. The patient should be instructed to seek prompt medical care if they experience any signs or symptoms of serious infection or hypersensitivity during therapy with ASPAVELI®, especially if indicative of infection with encapsulated bacteria. Sorbitol content: Patients with hereditary fructose intolerance should not be given ASPAVELI®. Sodium content: contains less than 1 mmol sodium (23 mg) per dose, that is to say, essentially 'sodium free'.

Interactions: Based on in vitro data, pegcetacoplan has low potential for clinical drug-drug interactions.

Fertility, pregnancy and lactation: Women of childbearing potential: It is recommended that effective contraception methods are used to prevent pregnancy during treatment and for at least 8 weeks after the last dose. Pregnancy: pegcetacoplan is not recommended during pregnancy and in women of childbearing potential not using contraception. Breast-feeding: It is recommended to discontinue breast-feeding during pegcetacoplan treatment.

Undesirable Effects: Consult section 4.8 of the SmPC for full details of undesirable effects including further information regarding infections, haemolysis, acute kidney injury, patients with post-transplant recurrent C3G or primary IC-MPGN and paediatric patients.

PNH: The most commonly reported adverse reactions in patients with PNH treated with pegcetacoplan were injection site reactions: injection site erythema, injection site pruritus, injection site swelling, injection site pain, injection site bruising. Other adverse reactions reported in more than 10% of patients during clinical studies were upper respiratory tract infection, diarrhoea, haemolysis, abdominal pain, headache, fatigue, pyrexia, cough, urinary tract infection, vaccination complication, pain in extremity, dizziness, arthralgia and back pain. The most commonly reported serious adverse reactions were haemolysis and sepsis.

Very common (≥1/10): upper respiratory tract infection (nasopharyngitis, upper respiratory tract infection, pharyngitis, rhinitis and sinusitis), urinary tract infection, haemolysis, headache, dizziness, cough, abdominal pain, diarrhoea, arthralgia, back pain, pain in extremity, infusion site reactions (infusion site erythema, infusion site pruritus, infusion site swelling, infusion site bruising, infusion site pain and infusion site induration) fatigue, pyrexia, infusion site pain, vaccination complication.

Common (≥1/100 to <1/10): sepsis, COVID-19, gastrointestinal infection, fungal infection, skin infection, oral infection, ear infection, infection, respiratory tract infection, viral infection, bacterial infection, vaginal infection, eye infection, thrombocytopenia, neutropenia, hypokalaemia, hypertension, dyspnoea, epistaxis, oropharyngeal pain, nasal congestion, nausea, erythema, rash, urticaria, myalgia, muscle spasms, acute kidney injury, chromaturia, , alanine aminotransferase increased, bilirubin increased.

Uncommon (≥1/1 000 to <1/100): anaphylactic shock, anaphylactic reaction, cervicitis, groin infection, pneumonia, nasal abscess, tuberculosis, oesophageal candidiasis, COVID-19 pneumonia, anal abscess.

C3G and primary IC-MPGN: The most commonly reported adverse drug reactions in patients with C3G or primary IC-MPGN treated with pegcetacoplan were infusion site reactions and upper respiratory tract infections. The most commonly reported serious adverse reactions were acute kidney injury and pneumonia.

Very common (≥1/10): Influenza, upper respiratory tract infection (nasopharyngitis, upper respiratory tract infection, pharyngitis, rhinitis and sinusitis), hypersensitivity reaction, headache, diarrhoea, nausea, acute kidney injury, pyrexia, infusion site reactions (infusion site erythema, infusion site pruritus, infusion site swelling, infusion site bruising, infusion site pain and infusion site induration).

Common (≥1/100 to <1/10): urinary tract infection, opportunistic infections, ear infection, pneumonia, thrombocytopenia, neutropenia, hypokalaemia, cough, epistaxis, pain in extremity, myalgia, fatigue.

Legal Category: Prescription Only Medicine (POM)

Marketing Authorisation Number(s): PLGB 30941/0022 (United Kingdom)

Pack size: each single pack contains 1 vial; Multipack containing 8 (8 packs of 1) vials**.**

Price: NHS list price £3,100 per pack of 1 vial, £24,800 per pack of 8 vials. **Marketing Authorisation Holder:** Swedish Orphan Biovitrum AB (publ), SE-112 76 Stockholm, Sweden.

Further information available from: Swedish Orphan Biovitrum (UK) Ltd, Suite 2, Riverside 3, Cambridgeshire, CB21 6AD

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▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. Reporting 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 reactions. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events 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.