USING EMPAVELI® ▼ (pegcetacoplan)

Guide for Healthcare Professionals

Please communicate the information outlined in this booklet to the patient/caregiver to ensure detection, careful monitoring, and proper management of selected safety concerns when prescribing EMPAVELI® (pegcetacoplan) in paroxysmal nocturnal haemoglobinuria (PNH).

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA

▼ 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.

Please see the Summary of Product Characteristics for EMPAVELI for more detailed safety information, in particular on serious infections caused by encapsulated bacteria.

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EMPAVELI® (pegcetacoplan)

Contents

Important information

EMPAVELI can only be distributed after written confirmation that the patient has received vaccinations against encapsulated bacteria including Streptococcus pneumoniae, Neisseria meningitidis types A, C, Y, W135, and type B, and Haemophilus influenzae type B 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 confirmation form.

The vaccination confirmation form should be sent to the CD coordinator who will then provide a unique controlled distribution reference number (CD reference number) for each patient. This reference number must be written onto the patient card and the patient will need to show the number at the pharmacy to receive EMPAVELI.

In order to contact the controlled distribution coordinator, please send an e-mail to: pv-me@sobi.com

Safety considerations

Risk of serious infection due to encapsulated bacteria

- Use of this medicinal product may predispose individuals to serious infections, especially those caused by encapsulated bacteria, such as Streptococcus pneumoniae, Neisseria meningitidis types A, C, Y, W135, and type B, and Haemophilus influenzae type B.
- Meningococcal infections may occur in patients treated with EMPAVELI and may become rapidly life- threatening or fatal if not recognised and treated as appropriate.
- Assess patients for early signs and symptoms of serious infection and treat patients immediately if an infection is suspected.

Vaccinations

- To reduce the risk of infection, all patients must be vaccinated against Streptococcus pneumoniae, Neisseria meningitidis types A, C, Y, W135, and type B, and Haemophilus influenzae type B within 2 years prior to starting EMPAVELI or according to applicable local vaccination guidelines.
- Vaccinate patients against encapsulated bacteria at least 2 weeks prior to administering the first dose of EMPAVELI, unless the risk of delaying therapy outweighs the risk of developing an infection.
- If immediate therapy with EMPAVELI is indicated, the required vaccines should be administered as soon as possible, and the patient should be treated with appropriate antibiotics 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 known infections.
- You will receive annual reminders to review the status of relevant vaccinations and mandatory revaccinations for patients in accordance with applicable local guidelines.

Risk of intravascular haemolysis after discontinuation and postponement of administration of the medicinal product

- After discontinuing the treatment with EMPAVELI, closely monitor for signs and symptoms of haemolysis, identified by elevated lactate dehydrogenase (LDH) levels along with 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.
- Monitor any patient who discontinues EMPAVELI for at least 8 weeks to detect haemolysis and other reactions.
- Inform patients who discontinue this treatment to keep the Patient Card with them for 8 weeks after the last dose, because the increased risk of serious infection persists for several weeks following discontinuation.

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

- The potential long-term effects of PEG accumulation are unknown.
- Regular laboratory testing of renal function is recommended.

What patients and caregivers need to know

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

- Risk of serious bacterial infections caused by encapsulated bacteria - if the patient experiences symptoms of serious bacterial infection, he/she should seek emergency medical treatment.

Signs and symptoms of serious bacterial 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

- The requirement to vaccinate against encapsulated bacteria or the use of antibiotic prophylaxis until the patient is vaccinated.
- The need to present the CD reference number on their patient card in order for the pharmacist to dispense EMPAVELI.
- Allergic reactions have been reported: if the patient experience symptoms of severe hypersensitivity reaction, he/she should seek emergency medical treatment.

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 after discontinuation and postponement of administration of the medicinal product.
- The Patient/Carer Guide and its content:
  - Provide the patient with the Patient Information Leaflet, Patient/ Carer Guide and Patient Card.
  - Inform the patient of the need to carry the Patient Card with them and to tell any healthcare practitioner that he/she is receiving treatment with EMPAVELI.

Adverse event reporting

Reporting suspected adverse events is important as it allows for continued monitoring of the benefit/risk balance of EMPAVELI. Report all adverse events including those of serious infections with encapsulated bacteria, severe hypersensitivity reactions and intravascular haemolysis after discontinuation of the medicinal product by contacting:

The National Pharmacovigilance Centre (NPC) - Saudi Food and Drug Authority (SFDA):

- SFDA call center: 19999
- E-mail: npc.drug@sfda.gov.sa
- Website: http://ade.sfda.gov.sa

Swedish Orphan Biovitrum AB (publ):

- Email: pv-ksa@sobi.com
- Website: Sobi in Middle East | Focus on Rare Diseases
- Phone no: +966 800 850 1523

More information

For more information about EMPAVELI contact:
Swedish Orphan Biovitrum AB (publ):

- Medical Information: pv-ksa@sobi.com

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