Generic name

**pegcetacoplan**

Empaveli

*Pharmaceutical company:* Apellis Pharmaceuticals

*Pharmacologic classification:* Complement inhibitor

*Therapeutic classification:* Immunomodulator

**AVAILABLE FORMS**

_Tablets:_ 1,080 mg/20 mL (54 mg/mL) single-dose vial

**INDICATIONS AND DOSAGES**

**Paroxysmal nocturnal hemoglobinuria (PNH)**

*Adults:* 1,080 mg subcut infusion twice weekly via infusion pump.

*Adjust-a-dose:* For LDH greater than twice the upper limit of normal, infuse 1,080 mg subcut every three days and monitor LDH twice weekly for at least 4 weeks. To reduce the risk of hemolysis with abrupt treatment discontinuation when switching from eculizumab, initiate pegcetacoplan while continuing eculizumab at its current dose; after 4 weeks, discontinue eculizumab and continue pegcetacoplan. When switching from ravulizumab, initiate pegcetacoplan no more than 4 weeks after the last dose of ravulizumab.

**CONTRAINDICATIONS AND CAUTIONS**

- **Black Box Warning:** Meningococcal infections may occur in patients treated with pegcetacoplan and may become rapidly life-threatening or fatal if not recognized and treated early. Use predisposes patients 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.
- **Black Box Warning:** Contraindicated in patients not currently vaccinated against encapsulated bacteria (including *S. pneumoniae*, *N. meningitidis* types A, C, W, Y, and B, and *H. influenzae* type B) unless the risk of delaying treatment outweighs the risk of developing such a bacterial infection.
- **Alert:** Contraindicated in patients with serious infection caused by encapsulated bacteria, including *S. pneumoniae*, *N. meningitidis*, and *H. influenzae*.
- **Black Box Warning:** Pegcetacoplan is available only through a REMS program. Prescribers must enroll in the program by phone (888-343-7073) or at www.empavelirems.com.
- Contraindicated in patients with hypersensitivity to pegcetacoplan or excipients.
- Hypersensitivity reactions (facial swelling, rash, urticaria) may occur. If a severe hypersensitivity reaction (including anaphylaxis) occurs, immediately discontinue infusion, treat per standard of care, and monitor until signs and symptoms resolve.
- Safety and effectiveness in children have not been established.
- **Dialyzable drug:** Unknown.

**PREGNANCY-LACTATION-REPRODUCTION**

- This drug may cause embryo-fetal harm. There are risks to the mother and fetus associated with untreated PNH in pregnancy. Consider use during pregnancy only if benefits outweigh risk.
- It is unknown whether this drug is present in human milk. Because of the potential for serious adverse reactions in a breastfed child, discontinue breastfeeding during treatment and for 40 days after the last dose.
- Pregnancy testing is recommended for females of reproductive potential prior to treatment.
- Female patients of reproductive potential should use effective contraception during treatment and for 40 days after the last dose.
INTERACTIONS
None reported.

ADVERSE REACTIONS
CNS: fatigue, headache.
CV: chest pain, hypertension.
GI: abdominal pain, diarrhea, intestinal ischemia, biliary sepsis.
Musculoskeletal: back pain.
Respiratory: respiratory tract infection, hypersensitivity pneumonitis.
Skin: injection site reaction.
Other: infection, viral infection.

Reactions in bold italics are life-threatening.

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