PATIENT CARD

ASPAVELI® (pegcetacoplan) ▼

Important information for patients taking ASPAVELI® (pegcetacoplan)

▼ 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 enclosed for details.

INFORMATION FOR PATIENTS

You have been prescribed pegcetacoplan as treatment for paroxysmal nocturnal haemoglobinuria. For more information on pegcetacoplan, refer to the pegcetacoplan Patient Information Leaflet and A Guide to Aspaveli (pegcetacoplan) for patients and caregivers.

Pegcetacoplan may increase your risk of getting serious and life-threatening infections. Serious infections may quickly become life-threatening and cause death if not recognised and treated early.

Call your doctor or nurse or get emergency care and show this card 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

Always keep this card with you during treatment and for 8 weeks after your last dose. Your risk of serious infections may continue for several weeks after your last dose.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the patient leaflet. Side effects can be reported directly to the Health Products Regulatory Authority (HPRA) using the available methods via www.hpra.ie. Side effects can also be reported to Swedish Orphan Biovitrum Ltd at medical.info.uk@sobi.com or by calling +44 (0) 800 111 4754.

By reporting side effects you can help provide more information on the safety of this medicine.

Show this card to any doctor, nurse or pharmacist involved in your care and if you go to hospital.

Patient name:

Carer name (if required):

Aspaveli (pegcetacoplan) prescriber name:

Aspaveli (pegcetacoplan) prescriber hospital:

Aspaveli (pegcetacoplan) prescriber phone number:

INFORMATION FOR HEALTHCARE PROFESSIONALS

This patient has a confirmed diagnosis of paroxysmal nocturnal haemoglobinuria and has been prescribed pegcetacoplan.

Pegcetacoplan may increase the patient's risk of serious bacterial infections such as *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type B infections.

- Serious bacterial infections may become rapidly life-threatening or fatal if not recognised and treated early.
- Closely monitor patients for early signs and symptoms of serious infection and evaluate immediately if infection is suspected. Promptly treat known infections.
- Contact the patient's prescribing physician (details given in this card) as soon as possible if any serious infection is suspected.

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.

For more information about pegcetacoplan, please refer to the full Summary of Product Characteristics.

Swedish Orphan Biovitrum Ltd,
Suite 2, Riverside 3, Granta Park,
Great Abington,
Cambridgeshire, CB21 6AD
www.sobi.com/uk/en

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