IRISH MEDICINES BOARD

Revlimid (lenalidomide) – risk of venous and arterial thromboembolic events

Revlimid (lenalidomide) is an immunomodulating agent first licensed via a European assessment procedure in 2007, subject to a number of risk minimisation measures to ensure its safe use. Structurally related to thalidomide, Revlimid is authorised for use in combination with dexamethasone for the treatment of multiple myeloma in patients who have received at least one prior therapy.

Multiple myeloma is an independent risk factor for thromboembolic complications. Evidence from clinical trials and case reports of adverse drug reactions suggests that lenalidomide may further increase the elevated risk of both venous and arterial thromboembolic reactions, including deep vein thrombosis, pulmonary embolism, myocardial infarction and cerebrovascular accident, in patients with myeloma. In reports of arterial and venous thromboembolic events received by the manufacturing authorisation holder, the use of thromboprophylaxis was not documented in most patients with a medically confirmed thromboembolic event, despite risk factors other than myeloma being identified.

Advice for healthcare professionals:

- Patients receiving lenalidomide should be closely monitored for evidence of arterial and venous thromboembolic events.
- Modifiable risk factors for thromboembolic events (e.g. smoking, hypertension, and hyperlipidaemia) should be managed wherever possible.
- Prophylactic anti-thrombotic medicines should be recommended, especially in patients with additional thrombotic risk factors (including prior thrombosis).
- Other agents that may increase the risk of thrombosis (e.g. oestrogen or erythropoietic agents) should be used with caution in multiple myeloma patients receiving lenalidomide.
- If a patient experiences any thromboembolic event, treatment with lenalidomide should be discontinued and anticoagulation therapy started. Once the patient has been stabilised on anticoagulation treatment and any complications of the thromboembolic event have been managed, lenalidomide may be restarted at the original dose, based on a benefit risk assessment. Anticoagulation should then be continued throughout the course of lenalidomide treatment.
- Patients should be instructed to seek medical care if they develop symptoms such as shortness of breath, chest pain, arm or leg swelling.

Key message:

In patients with multiple myeloma, the combination of lenalidomide and dexamethasone is associated with an increased risk of venous and arterial thromboembolism (predominantly deep vein thrombosis, pulmonary embolism, myocardial infarction and cerebrovascular accident).

Risk factors for thromboembolic events should be considered and managed wherever possible.

Appropriate thrombotic prophylaxis medication should be considered during lenalidomide treatment, particularly in patients with multiple thrombotic risks factors, after careful assessment of the balance of risks and benefits in individual patients.

Direct Healthcare Professional Communication has been issued by the manufacturing authorisation holder. Further information on the risks and benefits of lenalidomide can be found in the Summary of Product Characteristics available on www.imb.ie or in the European Public Assessment Report (EPAR) for lenalidomide on www.ema.europa.eu

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