

Lenalidomide (Revlimid) – Advice regarding viral reactivation

Lenalidomide (Revlimid) is an immunomodulatory agent similar to thalidomide and has antineoplastic, antiangiogenic and proerythropoietic properties. It is authorised for the treatment of adult patients with previously untreated multiple myeloma that are not eligible for transplant or in combination with dexamethasone in patients who have received at least one previous treatment. Lenalidomide is also indicated for the treatment of myelodysplastic syndromes and in patients with relapsed or refractory mantle cell lymphoma.

Viral reactivation, including herpes zoster and hepatitis B viruses (HBV), has been reported in the context of post-marketing monitoring of lenalidomide. Cases of hepatitis B reactivation have been reported across the EU very rarely (<1/10,000), but four cases did progress to hepatic failure. In these four cases, lenalidomide was discontinued and the patients required antiviral treatment. Previously infected patients should be closely monitored throughout therapy for signs and symptoms of viral reactivation, including active HBV infection.

Reactivation of herpes zoster led in some cases, to disseminated herpes zoster, meningitis herpes zoster or ophthalmic herpes zoster necessitating antiviral treatment and the permanent discontinuation or temporary discontinuation of treatment with lenalidomide.

Patients treated with lenalidomide usually have pre-existing risk factors for viral reactivation, including underlying progressive disease, older age and prior or concomitant treatment with immunosuppressive treatments including stem cell transplant. The immunosuppressive effect of lenalidomide may further increase the risk of viral reactivation in these previously infected patients.

Advice to Healthcare Professionals

- Cases of viral reactivation have been reported in patients treated with lenalidomide particularly in patients previously infected with herpes zoster or HBV.
- HBV status should be established before initiating treatment with lenalidomide.
- A doctor with expertise in the treatment of hepatitis B should be consulted for patients who test positive for HBV infection.
- Previously infected patients should be closely monitored for signs and symptoms of viral reactivation, including active HBV infection, throughout therapy.

Key Message

- There have been very rare reports of viral reactivation following treatment with lenalidomide. This has occurred particularly in patients previously infected with herpes zoster or hepatitis B viruses (HBV).
- Previously infected patients should be closely monitored throughout treatment with lenalidomide for signs and symptoms of viral reactivation.
- Pre-existing risk factors for viral reactivation include old age, an underlying progressive condition and prior or concomitant treatment with immunosuppressive treatments.
- All suspected adverse reactions associated with lenalidomide should be reported to the HPRA via the various reporting methods available (www.hpra.ie)

Further information on lenalidomide is available from www.hpra.ie and www.ema.europa.eu

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