

Otezla (apremilast) – Important advice regarding suicidal ideation and behaviour

Apremilast is a selective immunosuppressant medicine indicated for use alone or in combination with disease modifying antirheumatic drugs (DMARDs) for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response, or who have been intolerant to DMARD therapy previously. It is also indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to, or who have a contraindication to, or are intolerant to other systematic therapy including cyclosporine, methotrexate and ultraviolet-A light (PUVA).

It is important to note that suicidal behaviour-related events and depression are considered to occur more commonly in patients with psoriasis and psoriatic arthritis than in the general population. However, following a recent, thorough regulatory review of this issue, evidence from clinical trials and post-marketing experience suggests a causal association between suicidal ideation and behaviour with the use of apremilast.

Advice to Healthcare Professionals

- Suicidal ideation and behaviour have been reported from clinical trials and post-marketing experience (with or without a history of depression) with a frequency of uncommon ($\geq 1/1000$ to $\leq 1/100$), while cases of completed suicide were reported during the post-marketing period in patients taking apremilast.
- The balance of benefits and risks of treatment with apremilast should be carefully considered in patients with a history of psychiatric symptoms or patients taking medicines which are likely to cause psychiatric symptoms.
- Treatment with apremilast should be discontinued in patients who present with new or worsening psychiatric symptoms, or if suicidal ideation/suicidal behaviour is identified.
- Patients and carers should be informed of these risks and advised to contact the prescriber if any changes in mood or behaviour occur or in the case of any signs of suicidal ideation.
- The product information (Summary of Product Characteristics (SmPC) and Package Leaflet (PL)) for apremilast will be updated shortly.

Key message

- Following a regulatory review, evidence from clinical trials along with post-marketing experience suggests a causal association between suicidal ideation and behaviour with the use of apremilast.
- It is therefore recommended that the risks and benefits of commencing or continuing treatment with apremilast should be carefully assessed in patients with previous or existing psychiatric symptoms or if concomitant treatment with other medicinal products that are known to cause psychiatric effects.
- Patients and carers should be fully informed of these risks and advised to contact their doctor if symptoms emerge.
- All suspected adverse reactions associated with apremilast should be reported to the HPRA via the various reporting methods available (www.hpra.ie)

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

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