

Proton Pump Inhibitors (PPIs) – very rare reports of subacute cutaneous lupus erythematosus (SCLE)

Proton pump inhibitors (PPIs)* are indicated in the treatment of gastric and duodenal ulcers, NSAID-associated ulcers, gastro-oesophageal reflux, Zollinger-Ellison syndrome and in combination with antibacterial therapy for eradication of *Helicobacter pylori*. Some products are indicated for short-term use to treat reflux symptoms in adults (see individual SmPCs on www.hpra.ie for full details of licensed indications).

Reports of subacute cutaneous lupus erythematosus (SCLE) in association with PPIs have been reviewed by the European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC). The signal of an association was originally triggered by a retrospective medical chart review of patients diagnosed with SCLE over a 19-year period¹. Overall the cases were well documented with supporting biopsy and serological tests. These cases were supported by a case control study² which showed an increased risk of SCLE in patients exposed to PPIs.

Taking into consideration the relevant data across all substances in the class, including some cases with positive re-challenge, the evidence from published literature, and the likelihood of under-reporting given that photosensitivity is a known side-effect of PPIs, the PRAC agreed that the product information of medicinal products containing PPIs should be amended to reflect the risk of SCLE.

References

1. Sandholt LH, Laurinaviciene R, Bygum A. Proton pump inhibitor-induced subacute cutaneous lupus erythematosus. *Br J Dermatol.* 2014;170:342-51
2. Gronhagen CM, Forced CM, et al. Subacute cutaneous lupus erythematosus and its association with drugs: a population based matched case-control study of 234 patients in Sweden. *Br J Dermatology.* 2012; 167:296-305

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Advice for Healthcare Professionals

- PPIs are associated with very infrequent cases of SCLE. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by arthralgia, the patient should be advised to seek medical help promptly and the health care professional should consider stopping the PPI.
- SCLE after previous treatment with a PPI may increase the risk of SCLE with other PPIs.
- The product information (Summary of Product Characteristics (SmPC) and Package Leaflet (PL)) for all PPIs (prescription and non-prescription) will be updated to reflect this information.

Key message

PPIs are associated with very infrequent cases of SCLE.

**The active substances included in this review were omeprazole, esomeprazole, rabeprazole, pantoprazole, lansoprazole and dexlansoprazole. See www.hpra.ie for authorised product names and SmPCs for indications.*