HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Pregabalin – Expanded warning regarding drug dependence and withdrawal symptoms

Pregabalin-containing medicinal products* are authorised in Ireland and across the EU for the treatment of neuropathic pain in adults, as adjunctive therapy in adults for specific forms of epilepsy, and for generalised anxiety disorder in adults.

Product information** for pregabalin already includes a warning that cases of misuse, abuse and dependence have been reported and that caution should be exercised in patients with a history of substance abuse. Following a review of available data, the European Medicines Agency's (EMA's) Pharmacovigilance Risk Assessment Committee (PRAC) has expanded the warning to reflect that pregabalin can cause drug dependence, and that this may occur at therapeutic doses. Patients with a history of substance abuse may be at higher risk for pregabalin misuse, abuse and dependence.

Healthcare professionals (HCPs) should carefully evaluate an individual patient's risk of misuse, abuse and dependence before prescribing pregabalin. Patients treated with pregabalin should be monitored for symptoms of misuse, abuse or dependence, such as development of tolerance, dose escalation and drug-seeking behaviour.

The occurrence of withdrawal symptoms following discontinuation of pregabalin may indicate drug dependence. Symptoms reported include insomnia, headache, nausea, anxiety, diarrhoea, flu syndrome, nervousness, depression, pain, convulsion, hyperhidrosis and dizziness. Patients prescribed pregabalin should be informed of this at the start of the treatment. If pregabalin is discontinued, it is recommended this should be done gradually over a minimum of one week independent of the indication.

HCPs are reminded that pregabalin has also been associated with severe respiratory depression, including in the absence of concomitant opioid or other CNS depressant use in patients with and without risk factors for respiratory depression, as highlighted in HPRA Drug Safety Newsletter Edition 105. Dose adjustments may be necessary in patients at higher risk of respiratory depression (e.g. patients with compromised respiratory function, respiratory or neurological disease, renal impairment, concomitant use of CNS depressants, and in those of older age).

Key Message

- Pregabalin can cause drug dependence, which may occur at therapeutic doses.
- Patients with a history of substance abuse may be at a higher risk of pregabalin misuse, abuse and dependence.
- Patients prescribed pregabalin should be monitored for symptoms of misuse, abuse and dependence.
- The occurrence of withdrawal symptoms following discontinuation of pregabalin may indicate dependence.
- Patients prescribed pregabalin should be informed of this risk prior to commencing treatment.
- If pregbablin is to be discontinued, it is recommended this should be done gradually, over a minimum of one week, independent of the indication

**Further details on pregabalin-containing medicines including Lyrica and generics are available at www.hpra.ie and www.ema.europa.eu.*

***The approved product information is made up of the Summary of Product Characteristics (SmPC) and Package Leaflet (PL) and is available at www.hpra.ie and www.ema.europa.eu.*

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