HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Gabapentin and Pregabalin – Expanded warnings regarding the potential for abuse, dependence, and withdrawal symptoms

Gabapentin* and pregabalin* are authorised in Ireland and across the EU for the treatment of neuropathic pain in adults, and as therapies for specific forms of epilepsy in adults. Pregabalin is also authorised for generalised anxiety disorder in adults.

The product information** for both products already describe the risks of abuse, dependence, and withdrawal. Following separate reviews of the latest available data, the European Medicines Agency's (EMA's) Pharmacovigilance Risk Assessment Committee (PRAC) has recommended expanding existing warnings for both medicines in relation to drug dependence, including that this may occur at therapeutic doses. Patients with a history of substance abuse may be at higher risk of misuse, abuse, and dependence with gabapentin and pregabalin. Healthcare professionals (HCPs) should carefully evaluate an individual patient's risk of misuse, abuse, and dependence before prescribing these medications. Patients treated with gabapentin or pregabalin should be monitored for symptoms of misuse, abuse, or dependence, such as development of tolerance, dose escalation, and drug-seeking behaviour.

The product information is being updated to include a warning regarding the occurrence of withdrawal symptoms following discontinuation of gabapentin and pregabalin, including a full list of the types of symptoms experienced. Frequently reported withdrawal symptoms common to both medicines include:

- insomnia
- headache
- nausea
- anxiety
- depression
- pain
- hyperhidrosis/sweating
- dizziness

Withdrawal symptoms may indicate drug dependence and occur shortly after discontinuation. Gradual discontinuation is recommended over a minimum of one week, independent of the indication.

HCPs are also reminded that gabapentin and pregabalin have been associated with severe respiratory depression, and particular care is required in patients with and without risk factors for respiratory depression.

Key Message

- Drug dependence with gabapentin and pregabalin can occur at therapeutic doses.
- Patients with a history of substance abuse may be at a higher risk of misuse, abuse and dependence with gabapentin and pregabalin.
- Healthcare professionals should carefully evaluate an individual patient's risk of misuse, abuse, and dependence before prescribing gabapentin and pregabalin.
- Patients should be monitored for symptoms of misuse, abuse, or dependence such as development of tolerance, dose escalation, and drug-seeking behaviour.
- Withdrawal symptoms have been observed after discontinuation of short-term and long-term treatment with gabapentin and pregabalin. Withdrawal symptoms may indicate dependence.
- Patients should be alerted to these risks when treatment is commenced and be advised to monitor for signs of dependence.
- If gabapentin and pregabalin are to be discontinued, the dose should be reduced gradually over a minimum of one week.

** Further details on gabapentin- and pregabalin-containing medicines including Neurontin and Lyrica respectively 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).*