

20.10.2021 PREGABALIN İÇEREN İLAÇLAR-ACIL GÜVENLİLİK KISITLAMASI, ENG

MINISTRY OF HEALTH OF THE REPUBLIC OF TURKEY Medicines and Medical Devices Agency
of Turkey

20.10.2021

DOSSIER

The warning entitled “Pregabalin (Lyrica): Reports of severe respiratory depression”, published on the official website of the British Health Authority concerning the medicines containing Pregabalin has been evaluated by our Agency and it is necessary to add the following statements to the Summary of Product Characteristics of the referred medicines: “4.4. Special warnings and precautions for use” Respiratory Depression There have been reports of severe respiratory depression in relation to pregabalin use. Patients with compromised respiratory function, respiratory or neurological disease, renal impairment, those using CNS depressants concomitantly and the elderly may be at a risk of experiencing this adverse reaction more severely. Dose adjustment may be necessary in these patients (see section 4.2). “4.8. Undesirable effects” Respiratory, thoracic, and mediastinal disorders

Frequency: Unknown Respiratory depression I hereby submit for your information and kindly request for the conduct of relevant action so that any view, proposal, and contribution regarding the decision adopted is submitted to the Pharmacovigilance Risk Management Unit of the Department of Pharmacovigilance and Substances Subject to Control within 15 days as of the publication of the announcement and that no application is submitted to the Pharmacological Evaluation Unit during this period.

Assoc. Prof. Dr. Tolga KARAKAN President of the Agency

Distribution: For the adoption of relevant action: Turkish Pharmaceutical Industry Association Association of Research-Based Pharmaceutical Companies Pharmaceutical Manufacturers Association of Turkey Self-Care Products Association

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güvenlilik kısıtlaması