07 March 2023
EMA/96595/2023
EMEA/H/C/004277

Public statement

Pregabalin Zentiva k.s. (pregabalin)

Withdrawal of the marketing authorisation in the European Union

On 23 February 2023, the European Commission withdrew the marketing authorisation for Pregabalin Zentiva k.s. (pregabalin) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Zentiva k.s., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Pregabalin Zentiva k.s. was granted marketing authorisation in the EU on 27 February 2017 for the treatment of neuropathic pain, epilepsy and generalised anxiety disorder (GAD). The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2021.

Pregabalin Zentiva k.s. is a generic medicine of Lyrica. There are other generic medicinal products of Lyrica authorised and marketed in the EU.

The European Public Assessment Report (EPAR) for Pregabalin Zentiva k.s. will be updated to indicate that the marketing authorisation is no longer valid.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union