

21/4/2026

Levamisole-containing medicines will no longer be available on the EU market due to risk of leukoencephalopathy

Dear Healthcare professional,

The marketing authorisation holder in agreement with the European Medicines Agency and the DKMA would like to inform you of the following:

Summary

- **An EU-wide review concluded that levamisole can cause leukoencephalopathy.**
- **Considering that no effective measures have been identified to minimise the risk of leukoencephalopathy, the benefit-risk balance of levamisole-containing medicines is no longer favourable for the treatment of helminth infections.**
- **As a consequence, the marketing authorisations of these medicines are being withdrawn from the European Union market.**
- **Symptoms of leukoencephalopathy may occur in a period of one day to several months after treatment.**
- **Other anthelmintic therapeutic options are available**

Background on the safety concern

Levamisole is an imidazothiazole derivative, authorised as a fast-acting anthelmintic agent. It is indicated for the treatment of infections with the following worm species: *Ascaris lumbricoides*, *Necator americanus*, *Ancylostoma duodenale*, *Strongyloides stercoralis*, *Trichostrongylus colubriformis*.

Cases of leukoencephalopathy and central nervous system (CNS) demyelination have been reported following levamisole use, either in its authorised indication or in the context of off-label use, misuse or accidental exposure. An EU-wide review of the risk of leukoencephalopathy associated with levamisole-containing medicines was undertaken by EMA. This review included an evaluation of all available data including spontaneous post-marketing reports and the scientific literature, as well as consultation with a panel of independent experts in infectious diseases and neurology.

Following the evaluation of the available data, it was concluded that leukoencephalopathy may occur even after a single administration of levamisole in the approved indication and following treatment at the recommended dose. Furthermore, no risk factors could be clearly defined and no effective risk minimisation measures which could mitigate the risk were identified.

Levamisole-induced leukoencephalopathy is a severe adverse reaction that often requires an extensive and complex differential diagnostic assessment; this may postpone the start of adequate corrective treatment, leading to delayed patient recovery or recovery with sequelae. In patients presenting with

levamisole-induced leukoencephalopathy, neurologic symptoms varied according to the localisation of the lesions and included muscular weakness, language impairment, cognitive dysfunction, ataxia, paresis, among others. Intestinal helminth infections for which levamisole is used are generally mild and not life-threatening. Given the severity of leukoencephalopathy, a debilitating and potentially life-threatening, particularly if left untreated, the benefit-risk balance of levamisole-containing medicinal products for the treatment of intestinal helminth infections is no longer positive, and these medicines are being withdrawn from the EU market. Other anthelmintic therapeutic options are available in the EU.

Call for reporting

Your country may have specific processes in place to handle reports of adverse events. To report an adverse event to the local health authority, please contact your local health authority.