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News announcement

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 9-12 February 2026

PRAC concludes safety review of levamisole, a medicine used to treat parasitic worm infections

PRAC recommends withdrawal of marketing authorisations for levamisole medicines

Leukoencephalopathy confirmed as a serious side effect of levamisole

EMA's safety committee, the PRAC, has recommended that medicines containing levamisole be withdrawn from the EU market. This follows an EU-wide safety review which concluded that the benefits of these medicines no longer outweigh their risks for the treatment of parasitic worm infections due to the risk of leukoencephalopathy, a rare but serious side effect of levamisole that affects the brain's white matter.

The information reviewed showed that symptoms of leukoencephalopathy may occur after a single dose of levamisole and may develop within one day up to several months after treatment. The review did not identify any measures to reduce the risk or any group of people who may be at higher risk of developing leukoencephalopathy with levamisole use. Overall, considering that levamisole medicines are used to treat mild parasitic worm infections, and that levamisole-induced leukoencephalopathy is a serious condition with an unpredictable onset, the benefit–risk balance of these medicines was considered negative.

More information is available in EMA's public health communication: https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-9-12-february-2026

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