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EMA recommends withdrawal of marketing authorisations for levamisole medicines

Leukoencephalopathy confirmed as a serious side effect of levamisole

On 26 March 2026, the CMDh[1] endorsed the recommendation made by EMA's safety committee (PRAC) to withdraw medicines containing levamisole from the EU market. This follows an EU-wide review which concluded that the benefits of these medicines no longer outweigh their risks for the treatment of parasitic worm infections in adults and children.

The review confirmed that leukoencephalopathy is a rare but serious side effect of levamisole. Leukoencephalopathy damages the white matter of the brain, which is made of nerve fibres covered by myelin, a protective layer that allows efficient communication between different parts of the brain. This condition can be debilitating and life-threatening, particularly if left untreated, and its diagnosis is complex.

The information reviewed by PRAC showed that leukoencephalopathy can occur after a single dose of levamisole and that symptoms may develop 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 or lower risk. In addition, other medicines are authorised in the EU for the treatment of parasitic worm infections. Given that levamisole medicines are used to treat mild parasitic worm infections, and that levamisole-induced leukoencephalopathy is a serious condition with an unpredictable onset, PRAC concluded that the benefits of levamisole medicines no longer outweigh the risks and recommended that their marketing authorisations be withdrawn in the EU.

The PRAC recommendation is based on the assessment of new data gathered through the continuous safety monitoring of medicines authorised in the EU. These included reports of serious cases of leukoencephalopathy and demyelination of the central nervous system (loss of myelin in the brain and spinal cord) following use of levamisole, as well as a review of the published scientific literature. The PRAC also considered input from a panel of independent experts in infectious diseases and neurologists, and from the World Health Organization.

EMA continuously monitors the safety of medicines authorised in the EU. When new evidence shows that a medicine's risks may outweigh its benefits, the Agency acts to protect public health. The

[1] The CMDh is a body representing EU Member States as well as Iceland, Liechtenstein and Norway. It is responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU.

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recommendation to withdraw medicines containing levamisole reflects EMA's commitment to ensuring that medicines available in the EU meet robust standards of safety, effectiveness and quality.

Information for patients

- EMA recommended that medicines containing levamisole are withdrawn from the EU market. In some EU countries, these medicines are authorised to treat parasitic worm infections.
- A review by EMA's safety committee (PRAC) confirmed that medicines containing levamisole can cause leukoencephalopathy, a serious side effect which damages parts of the brain.
- Other medicines are available in the EU for the treatment of parasitic worm infections.
- People who have been treated with medicines containing levamisole should seek medical advice immediately if they develop muscle weakness, difficulty speaking, confusion or difficulty controlling movements.
- These symptoms can occur after a single dose of levamisole and may develop up to several months after treatment with a levamisole medicine.
- If you have questions about your or your child's past or present treatment with a medicine containing levamisole, please contact your doctor.

Information for healthcare professionals

- EMA recommended that medicines containing levamisole are withdrawn from the EU market. In some EU countries, these medicines are authorised as anthelminthics.
- A review by EMA's safety committee (PRAC) confirmed that levamisole can cause leukoencephalopathy, a serious adverse reaction with unpredictable onset.
- Symptoms of leukoencephalopathy can occur after a single dose of levamisole and may develop up to several months after treatment.
- In patients with levamisole-associated leukoencephalopathy, neurologic symptoms vary depending on the localisation of the lesions and may include muscular weakness, language impairment, cognitive dysfunction, ataxia and paresis.
- Other anthelminthic treatments are authorised in the EU.
- EMA's recommendation is based on an EU-wide review of spontaneous reports of leukoencephalopathy and central nervous system demyelination following levamisole use, either in its authorised indication or in the context of off-label use, misuse or accidental exposure, a review of the scientific literature and input from a panel of independent experts in infectious diseases and neurology.
- A direct healthcare professional communication (DHPC) will be sent to relevant healthcare professionals and published on a dedicated page on the EMA website.

More about the medicine

Levamisole is an anthelminthic, a medicine used in adults and children to treat infections caused by the following parasitic worms: *Ascaris lumbricoides*, *Necator americanus*, *Ancylostoma duodenale*, *Strongyloides stercoralis* and *Trichostrongylus colubriformis*.

Levamisole works mainly by stimulating nicotinic acetylcholine receptors, which are proteins found on the surface of the worm's nerve cells. This leads to rapid paralysis of the worm's muscles, preventing movement and allowing it to be expelled from the gut of the infected person.

Medicines for human use containing levamisole are available as tablets to be taken by mouth, generally as a single dose. They are authorised in Hungary, Lithuania, Latvia and Romania under the trade names Decaris and Levamisol Arena.

More about the procedure

The review of medicines containing levamisole was initiated at the request of the Romanian medicines agency (NAMMDR), under Article 31 of Directive 2001/83/EC.

The review was carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which made a recommendation. As medicines containing levamisole have all been authorised via national procedures, the PRAC recommendation was sent to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which has adopted a position on 26 March 2026. The CMDh is a body representing EU Member States as well as Iceland, Liechtenstein and Norway. It is responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU. Because the CMDh adopted its position by consensus, the PRAC recommendation will be directly implemented by the Member States where the medicines are authorised, according to an agreed timetable.