正本

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衛生福利部食品藥物管理署　函

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擬公告學會網站

林雅琪 7/24

主旨：有關本署啟動含levamisole成分藥品之臨床效益及風險再評估一案，詳如說明，請查照。

說明：

一、因歐洲醫藥管理局EMA-PRAC經評估後確認腦白質病變（leukoencephalopathy）為levamisole之嚴重不良反應，認為使用levamisole治療成人和兒童的寄生蟲感染之臨床效益不再大於其風險，決議撤銷含levamisole成分藥品於歐盟之上市許可。

二、為進行含levamisole成分藥品之臨床效益及風險再評估，貴會倘有相關意見或下列相關研究文獻等資料，請於115年8月28日前檢送至本署，逾期未提具資料者，視同無意見：

(一)請提供旨揭成分藥品臨床風險效益之見解，及我國現今臨床實際常用情形(如寄生蟲感染、復發性口腔潰瘍、大腸

直腸癌或其他使用levamisole治療之疾病)。

(二)請針對使用旨揭成分藥品後發生腦白質病變之風險提供臨床見解。

(三)若於國內暫停販售或下市旨揭成分藥品，對於臨床(包含各醫療機構層級)可能造成之衝擊影響?針對其臨床使用情形(如寄生蟲感染、復發性口腔潰瘍、大腸直腸癌之治療等)，是否有其他可替代藥品?

(四)或是否建議仿單「加框警語」、「警語及注意事項」及「不良反應」處加刊「腦白質病變」相關安全性資訊？

(五)其他意見或建議。

正本：中華民國醫師公會全國聯合會、中華民國藥師公會全國聯合會、中華民國藥劑生公會全國聯合會、中華民國基層醫療協會、台灣藥物臨床研究協會、台灣家庭醫學醫學會、臺灣醫學會、社團法人臺灣臨床藥學會、台灣內科醫學會、台灣感染症醫學會、社團法人中華民國牙醫師公會全國聯合會、台灣臨床腫瘤醫學會、台灣消化系醫學會、台灣耳鼻喉頭頸外科醫學會、臺灣皮膚科醫學會、社團法人中華民國風濕病醫學會、臺灣兒科醫學會、台灣小兒消化醫學會、社團法人台灣臨床腫瘤醫學會、台灣腎臟醫學會、台灣兒童腎臟醫學會

副本：衛生福利部中央健康保險署、財團法人醫藥品查驗中心、全國藥物不良反應通報中心(均含附件)

署長 姜至剛

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EMA recommends withdrawal of marketing authorisations for levamisole medicines

13 February 2026

Leukoencephalopathy confirmed as a serious side effect of levamisole

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EMA's safety committee (PRAC) recommended that medicines containing levamisole be withdrawn from the EU market.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 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 the page Direct healthcare professional communications (DHPC) 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 has been carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which made a set of recommendations. The PRAC recommendations will now be sent to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a position. 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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Pharmacovigilance Risk Assessment Committee (PRAC)

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27 March 2026
EMA/31681/2026

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

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- 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.
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- 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.
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- 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

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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.