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

Review will assess risk of leukoencephalopathy, a condition affecting the brain

EMA's safety committee (PRAC) has started a review of medicines containing levamisole, authorised in four countries of the European Union (EU) to treat infections caused by parasitic worms in adults and children.

The review follows concerns about a risk of leukoencephalopathy with levamisole, a potentially serious condition that damages the white matter of the brain. White matter is made of nerve fibres covered by a protective layer called myelin, which allows efficient communication between different parts of the brain. Leukoencephalopathy can be life-threatening and debilitating, especially when left undiagnosed or untreated. It may lead to a range of neurological symptoms, including but not limited to, confusion, weakness or impaired muscle function, difficulties with movement coordination, and impaired or lost speech or vision.

Leukoencephalopathy has already been identified as a potential risk with levamisole, and the product information of levamisole medicines include the general term encephalopathy (a group of brain dysfunction conditions).

The review follows new data gathered as part of the continuous safety monitoring of medicines authorised in the EU. These include reported serious cases of leukoencephalopathy following levamisole use, one of which resulted in death, as well as additional data published in the medical literature. PRAC will review all available evidence regarding the risk of leukoencephalopathy with medicines containing levamisole, including any risk minimisation measures already in place. Because some of the reported cases describe demyelination in the central nervous system (loss of myelin in the brain and spinal cord) which is a form of leukoencephalopathy, the review will also address this safety concern.

The committee will also assess the impact of the risk of leukoencephalopathy and demyelination on the benefit-risk balance of these medicines and issue a recommendation on whether their marketing authorisations should be maintained, varied, suspended or withdrawn across the EU.

More about the medicine

Levamisole is an anthelmintic, 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*.

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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 containing levamisole are available as tablets to be taken by mouth, generally in 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 is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations.

The PRAC recommendations will then 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 in the EU. If the CMDh position is adopted by consensus, the recommendations of the PRAC will be directly implemented in all Member States where the medicines are authorised. If the CMDh position is adopted by majority vote, the CMDh position will be sent to the European Commission, which will issue a final legally-binding decision applicable in all EU Member States.