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Levamisole-containing anthelmintic medicine Decaris, tablets 50 mg and 150 mg will no longer be available on the market due to risk of leukoencephalopathy

Dear Healthcare professional,

Representative Office of Gedeon Richter Plc., in Republic of Armenia in agreement with the Centre of Drug and Medical Technology Expertise 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 As a consequence, the marketing authorisations of these medicines are being withdrawn.
- 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*.

Cases of leukoencephalopathy and 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 European Medicines Agency. 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 helminthic 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 helminthic infections is no longer positive, therefore Decaris, tablets 50 mg and 150 mg are being withdrawn from the Armenian market. Other anthelmintic therapeutic options are available.

Information for Patients

- European Medicines Agency (EMA) recommended that medicines containing levamisole are withdrawn. These medicines are authorised to treat parasitic worm infections.

- A review by EMA's safety committee confirmed that medicines containing levamisole can cause leukoencephalopathy, a rare but serious side effect which damages parts of the brain.

- Other medicines are available 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 used Decaris and have questions about your past or present Decaris treatment, please contact your doctor.

- Please refrain from self-medication. Especially without prior appropriate tests and without consulting a doctor. Medications should be used according to the indications which are defined in the instructions for use, in compliance with the dose prescribed by your doctor.

Call for reporting

It is important to report suspected adverse reactions in order to ensure continuous monitoring of the benefit-risk balance of the medicinal product. It is recommended to report any suspected adverse reactions through the national spontaneous reporting system:

Centre of Drug and Medical Technology Expertise

Official website: www.pharm.am

Email address: vigilance@pharm.am

*Hotline: +374 10 20 05 05,
+374 96 22 05 05.*

Company contact details

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