<Date>

Levamisole-containing medicines will no longer be available on the EU market due to risk of leukoencephalopathy

Dear Healthcare professional,

<Name of marketing authorisation holder> in agreement with the European Medicines Agency and the <National Competent Authority > 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- **As a consequence, the marketing authorisations of these medicines are being withdrawn from the European Union market.**
- **Symptoms of leukoencephalopathy may occur in a period of one day to several months after treatment.**
- **Other anthelminthic therapeutic options are available (to be adapted at national level accordingly).**
- **<Recall information including level (pharmacy or patient) and date of recall – to be agreed at National Level>**

Background on the safety concern

Levamisole is an imidazothiazole derivative, authorised as a fast-acting anthelminthic agent. It is indicated for the treatment of infections with the following worm species <to be listed in accordance with therapeutic indication approved nationally>: <*Ascaris lumbricoides, Necator americanus, Ancylostoma duodenale, Strongyloides stercoralis, Trichostrongylus colubriformis*>.

Cases of leukoencephalopathy and central nervous system (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 EMA. 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 disfunction, ataxia, paresis, among others. Intestinal helminth 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 helminth infections is no longer positive, and these medicines are being withdrawn from the EU market. Other anthelminthic therapeutic options are available in the EU.

<National recall – to be included nationally>

Call for reporting

<A reminder of the need and how to report adverse reactions in accordance with the national spontaneous reporting system, including the details (e.g. name, postal address, fax number, website address) on how to access the national spontaneous reporting system>

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Levamisole-containing medicinal products
Marketing authorisation holder(s)	Arena Group S.A.; Gedeon Richter Plc.
Safety concern and purpose of the communication	Levamisole-containing medicines will no longer be available on the EU market due to risk of leukoencephalopathy.
DHPC recipients	General practitioners, infectious disease specialists/specialists in parasitic infections, neurologists, paediatricians, pharmacists. The target group should be further defined at national level, in agreement with the respective national competent authority.
Member States where the DHPC will be distributed	All EU member states where levamisole-containing medicinal products are authorised, for other member states to be decided at national level.

Timetable	Date
DHPC and communication plan (in English) agreed by PRAC	12 February 2026
DHPC and communication plan (in English) agreed by CMDh	26 March 2026
Submission of translated DHPCs to the national competent authorities for review	CMDh position/EC decision (as applicable) + 7 calendar days
Agreement of translations by national competent authorities	CMDh position/EC decision (as applicable) + 14 calendar days
Dissemination of DHPC	CMDh position/EC decision (as applicable) + 21 calendar days