IRISH MEDICINES BOARD

Lariam (mefloquine): Updated product information and availability of guidelines for healthcare professionals/ alert cards for patients

Lariam (mefloquine) is an anti-malarial product currently authorised in Ireland for:

- The treatment of *P. Falciparum* malaria in which the pathogen has become resistant to other anti-malarial agents.
- For chemoprophylaxis i.e. prophylaxis of malaria in people travelling to malarious areas in which multiple resistant *P. Falciparum* strains occur.

The potential for Lariam to induce serious neuropsychiatric disorders was first identified a number of years ago and has been the subject of previous reviews/updates at European and national level. As part of the on-going monitoring of its benefits and risks, a further review of cumulative safety data was concluded at EU level in April 2013. This review confirmed the known risks associated with use of mefloquine and recommended strengthened warnings and updates to the product information to be supplemented with educational materials.

These supplementary materials should be read in conjunction with the current version of the Summary of Product Characteristics (SmPC), which is available at www.imb.ie. Healthcare Professionals are additionally reminded of the following recommendations:

- Lariam must not be used for malaria chemoprophylaxis in patients with active or a history of psychiatric disturbances (see SmPC for details of contraindications and warnings).
- Lariam may induce potentially serious neuropsychiatric disorders.
- The most common neuropsychiatric reactions include abnormal dreams, insomnia, anxiety, and depression. Additionally hallucinations, psychosis, suicide, suicidal thoughts and self-endangering behaviour have been reported.
- Patients should be advised that if they experience a neuropsychiatric reaction such as suicidal thoughts; self-endangering behaviour; severe anxiety; feelings of restlessness, confusion, or mistrust towards others; visual/ auditory hallucinations; depression; or changes to their mental state during treatment, they should stop taking Lariam immediately and seek medical advice immediately.
- Healthcare professionals should react promptly to signs of neuropsychiatric reactions with Lariam, evaluating patients and, as appropriate, discontinuing treatment and replacing it with alternative malaria prophylaxis medication.
- Adverse reactions may occur at any time during treatment, and due to the long half life may persist after discontinuation.
- The Guide for Healthcare Professionals should be read and the checklist followed before prescribing Lariam for any patient.

Advice to Healthcare Professionals

- Be aware of the prescribing recommendations and contraindications for the appropriate use of Lariam as outlined in the SmPC.
- A guide for healthcare professionals entitled "Lariam (Mefloquine) for Malaria Chemoprophylaxis", a checklist for the prescription of Lariam and a Lariam patient alert card have all been made available by the Marketing Authorisation Holder.
- These prescribing tools are intended to act as a resource to aid prescribing decisions and monitoring in patients and should be used in conjunction with the prescribing information. A "Lariam patient alert card" should be given to all patients.
- Please report suspected adverse reactions associated with use of Lariam to the IMB, via the online reporting/downloadable form options (www.imb.ie), or by telephone (01-6764971).

Key message

- Mefloquine has been associated with serious neuropsychiatric adverse effects.
- Patients, caregivers, and health care professionals should watch for these types of effects and patients should be advised to urgently contact a healthcare professional if they develop neuropsychiatric adverse reactions during treatment.

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