Recommendation for the update of patient and prescriber information for Pradaxa

14.06.2012 | Circular P11/2012

Pradaxa

Pradaxa contains the active ingredient dabigatran and is an anticoagulant medicine which prevents blood from clotting. It is prescribed to adults who have had hip or knee replacement surgery to prevent venous thromboembolic events (thrombosis) and also to patients with non-valvular atrial fibrillation (irregular heart beat) to prevent stroke and other obstructions to blood vessels. Pradaxa was first authorised in the EU in March 2008 and is marketed in all EU states, including Malta.

Information from European Medicines Agency about the safety concern

This risk of bleeding with anticoagulant medicines including Pradaxa was known at the time of authorisation and has been kept under close review by the European Medicines Agency's Committee for Human Medicinal Products (CHMP), which has monitored the number of serious bleedings reported with Pradaxa since its authorisation, including fatal cases. In January 2012, further precautions were included in the prescribing information following reports of fatal cases of bleeding which occurred in Japan. The updates focused on patients with reduced kidney function, as dabigatran is eliminated by the kidneys and a reduced function can lead to an increased amount of dabigatran in the bloodstream, increasing the risk of bleeding. In January 2012 the CHMP decided that an in-depth assessment of the latest available data was appropriate to determine if the risks were any greater than understood at the time of authorisation, and if the prescribing information could be further strengthened to increase the safety of patients.

Based on this assessment the CHMP is of the opinion that;

- On the basis of the available evidence, the benefits of Pradaxa continue to outweigh its risks and that it remains an important alternative to other blood-thinning agents.

Medicines Authority
203 Level 3, Rue D'Argens, Gzira, GZR 1368 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 www.medicinesauthority.gov.mt

- Advice to doctors and patients should be updated and strengthened to give clearer guidance on the best use of the medicine. This includes more specific guidance when Pradaxa must not be used as well as advice on managing patients and reversing the anticoagulant effect of Pradaxa if bleeding occurs.
- Updating the product information for Pradaxa, to give clearer guidance to doctors and patients on how to reduce and manage the risk of bleeding associated with the anticoagulant medicine.

A European Commission decision on the CHMP opinion will be issued in due course.

In Malta

For Healthcare Professionals

- Boehringer Ingelheim has submitted a Prescribers Educational Pack and Patient Alert Card which the Medicines Authority has reviewed and approved.
- The approved pack is to be distributed to all General Practitioners, Cardiologists, Haematologists, Neurologists and Geriatricians by Boehringer Ingelheim medical representatives in hard copy.

The Medicines Authority together with the marketing authorization holder Boehringer Ingelheim and representatives in Malta will continue to increase the awareness amongst healthcare professionals on the potential risk of bleeding during treatment with Pradaxa and will continue to give guidance on how to manage that risk.

Advice for patients

- Patients who are taking Pradaxa, or any other blood thinner, should be aware that they are at an increased risk of bleeding.
- If they fall or injure themselves during treatment, especially if they hit their head, they should seek urgent medical attention.
- Patients should also be informed on the signs and symptoms of bleeding such as bleeding under the skin, tar-coloured stools, blood in urine, nose bleeds, etc.
- Patient alert cards are to be given when treatment with Pradaxa is started and patients should be advised to keep it on them at all times. .

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For more information please see the **press release** and **question-and-answer document** issued by the European Medicines Agency and the current European public assessment report for Pradaxa which can be found on the Agency's website: **ema.europa.eu/Find medicine/Human medicines/European public assessment reports.**

Reporting adverse drug reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Pradaxa. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority yellow card scheme or online at **http://www.medicinesauthority.gov.mt/pub/adr.doc** or to the marketing authorisation holder or their local representatives.

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

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