Review of Procoralan® started

23.06.2014 | Circular Number P18/2014

Information on Procoralan®

- Procoralan is a medicine containing the active substance ivabradine and is used to treat symptoms of long-term stable angina in adults with coronary heart disease who have a normal heart rhythm.
- It works by lowering the heart rate thereby reducing the stress on the heart and slowing the progression of heart failure and reducing or preventing the symptoms of angina.
- Procoralan is also used in patients with long-term heart failure who have a normal heart rhythm but whose heart rate is at least 75 beats per minute.
- Procoralan was authorised in all EU member states in 2005 via the centralised procedure. In some member states but not Malta, this medicine is marketed under trade-name Corlentor®.
- The European Medicines Agency has started a review of the medicine Corlentor/Procoralan (ivabradine). Corlentor/Procoralan is used to treat the symptoms of adults with long-term stable angina (chest pain due to obstruction in the arteries in the heart) or long-term heart failure (when the heart cannot pump enough blood to the rest of the body).

Information from the European Medicines Agency about the safety concern

The review follows preliminary results from the SIGNIFY study, which was evaluating whether treatment with Procoralan in patients with coronary heart disease reduces the rate of cardiovascular events (such as heart attack) when compared with placebo (a dummy treatment). Healthcare professionals can access the trial site on http://signify-study.com

In this trial patients received up to 10 mg twice daily, a dose which is higher than the currently authorised maximum daily dose (7.5 mg twice daily). The results showed a small but significant increase in the combined risk of cardiovascular death or non-fatal heart attack with the medicine in a subgroup of patients who had symptomatic angina (Canadian Cardiovascular Society class II - IV).

The European Medicines Agency will now evaluate the impact of the data from the SIGNIFY study on the balance of benefits and risks of Procoralan and issue an opinion on whether the marketing authorisation should be maintained, varied, suspended or withdrawn across the EU.

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While the review is ongoing and pending further communication, patients should speak to their doctor or pharmacist if they have any questions or concerns. Doctors and pharmacists received a Direct Healthcare Professional Communication sent by Galepharma ltd. on behalf of the Marketing Authorisation Holder *Les Laboratoires Servier* which gave more detailed information on the safety concern. This letter can also be accessed on the Medicines Authority website at **www.medicinesauthority.gov.mt/dhpc.**

For more information on Procoralan please visit **www.ema.europa.eu**

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Procoralan containing medicines. Suspected Adverse Drug Reactions (side effects)or medication errors may be reported using the Medicines Authority ADR reporting form or online at **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Prof. John J Borg PhD (Bristol)
Post-licensing Director

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

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