



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 November 2013
EMA/CHMP/712673/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Procoralan ivabradine

On 21 November 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Procoralan. The marketing authorisation holder for this medicinal product is Les Laboratoires Servier. They may request a re examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a change to a contraindication as follows:

“Pregnancy, lactation and women of child-bearing potential not using appropriate contraceptive measures (see section 4.6)”

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full contraindications for Procoralan will be as follows²:

- **“Hypersensitivity to the active substance or to any of the excipients listed in section 6.1**
- **Resting heart rate below 60 beats per minute prior to treatment**
- **Cardiogenic shock**
- **Acute myocardial infarction**
- **Severe hypotension (< 90/50 mmHg)**
- **Severe hepatic insufficiency**
- **Sick sinus syndrome**

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.

² The text in bold represents the new or the amended contraindication.



- Sino-atrial block
- Unstable or acute heart failure
- Pacemaker dependent (heart rate imposed exclusively by the pacemaker)
- Unstable angina
- AV-block of 3rd degree
- Combination with strong cytochrome P450 3A4 inhibitors such as azole antifungals (ketoconazole, itraconazole), macrolide antibiotics (clarithromycin, erythromycin *per os*, josamycin, telithromycin), HIV protease inhibitors (nelfinavir, ritonavir) and nefazodone (see sections 4.5 and 5.2)
- Pregnancy, lactation **and women of child-bearing potential not using appropriate contraceptive measures** (see section 4.6)“