



March 2018

Procoralan[®] (Ivabradine)

Direct Healthcare Professional Communication on the re-registration of Procoralan with new restriction to Chronic Heart Failure indication.

Dear Healthcare Professional,

We would like to inform you that SFDA agreed in March 2017 on the re-registration of PROCORALAN[®] (Ivabradine 5 and 7.5 mg) in Saudi Arabia in the following indication:

Ivabradine is indicated to reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction $\leq 35\%$, who are in sinus rhythm with resting heart rate ≥ 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use.

and allowed PROCORALAN[®] to be available for 22 cardiac centers in the Kingdom (as listed at the end of the present letter).

For a safe use of Procoralan[®], Health care professionals should be aware of the following:

- **Procoralan[®] should not be used in patients with resting heart rate < 70 bpm prior to treatment.**
- **The usual recommended starting dose of ivabradine is 5 mg twice daily in patients < 75 years (and 2.5 mg twice daily in patients ≥ 75 years). The maintenance dose should not exceed 7.5 mg twice daily.**
After two weeks of treatment, the dose should only be increased to 7.5 mg twice daily (5 mg twice daily in patients ≥ 75 years) if resting heart rate is persistently > 60 bpm or decreased to 2.5 mg twice daily if resting heart rate is persistently < 50 bpm or in case of bradycardia.
- If, during treatment, heart rate decreases below 50 bpm or in case of bradycardia symptoms, the dose must be titrated downward (and discontinued if it persists despite dose reduction).
- **Prior to treatment initiation or when considering titration, the heart rate should be monitored frequently, including serial heart rate measurements, ECG, or ambulatory 24-hour monitoring.**
- **Concomitant use of ivabradine with strong cytochrome P450 3A4 inhibitors and heart rate-reducing calcium channel blockers such as verapamil or diltiazem is contraindicated.**
- **Procoralan[®] is not recommended in patients with atrial fibrillation or other cardiac arrhythmias that interfere with sinus node function. Procoralan[®]-treated patients should be regularly monitored for the occurrence of atrial fibrillation. If atrial fibrillation develops during treatment, the balance of benefits and risks of continued ivabradine treatment should be carefully reconsidered.**

- **The use of ivabradine in patients with congenital QT syndrome or treated with QT prolonging medicinal products should be avoided.** If the combination appears necessary, close cardiac monitoring is needed. Heart rate reduction, as caused by ivabradine, may exacerbate QT prolongation, which may give rise to severe arrhythmias, in particular Torsade de pointes.

In order to provide you and your patients with information and recommendations regarding the appropriate and safe use of Procoralan[®], please be informed that a prescriber guide and a patient guide are at your disposal.

This information has been agreed with the Saudi Food and Drug Authority.

Call for reporting

As a reminder, there is a need to report any suspected adverse reactions to the National Pharmacovigilance and Drug Safety Centre or Pharmacovigilance department in Servier, according to the following;

Calling: 19999

By e-mail: npc.drug@sFDA.gov.sa

Or by fax: +966 11 2057662

Or by online: <https://ade.sFDA.gov.sa/>

LPV: Mohammed Alotaibi

E-mail: mohamed.alotaibi@servier.com

Fax no. : +966 (11) 2886811

Tel.: +966 11 2886813 Ext. 103

Mobile: +966 537550388

Yours sincerely,



Marie-Dominique FRATACCI-SIBILLE, MD.
Pharmacovigilance
European Qualified Person



Patricia MAILLERE
General Director
Worldwide Regulatory Affairs

1. King Fahad Cardiac Center, King Saud University, Riyadh	11. Prince Sultan Cardiac Center, Hafouf
2. Prince Salman Heart Center, King Fahd Medical City, Riyadh	12. King Fahad Specialist Hospital, Dammam
3. Prince Sultan Cardiac Center, Riyadh	13. Armed Forces Hospital Southern Region, Khamis Mushayt
4. National Guard Hospitals,(Riyadh, Jeddah, Dammam, Hofuf)	14. North West Armed Forces Hospital, Tabuk
5. King Fahad Hospital, Jeddah	15. Asser Central General hospital, Abha
6. King Saud Medical Complex, Riyadh	16. Mouwasat Hospital (Dammam,Jubail, Madinah, Qatif, Riyadh)
7. Aramco Medical Center, Dhahran	17. Dr Sulaiman AlHabib Hospital Riyadh(Olaya , Takhassusi, Arryan)
8. King Faisal Cardiac Center, King Faisal Specialist Hospital (Riyadh,Jeddah)	18. Saudi German Hospitals (Jeddah, Riyadh, Madina, Khamis)
9. Saud Al-Babtain Cardiac Centre-Dammam	19. International Medical Center, Jeddah
10. King Fahad Armed Forces Hospital , Jeddah	20. Dr Sulaiman Fakeeh Hospital Jeddah
	21. Dallah Hospital ,Riyadh
	22. Almana Hospitals (Khobar,Jubail,Dammam)