SFDA SAFTEY COMMUNICATION

Dec 26th , 2012

Saudi Food and Drug Authority (SFDA) PRESS RELEASE- Dabigatran (Pradaxa®) is Now Contraindicated in Patients with Mechanical Prosthetic Heart Valves

The Saudi Food and Drug Authority (SFDA) would like to inform you about important new safety information related to the use of dabigatran (Pradaxa®) in patients with mechanical prosthetic heart valves. Pradaxa® should **NOT** be used to prevent stroke or blood clots in patients with mechanical prosthetic heart valves and any patient with mechanical prosthetic heart valves who is taking Pradaxa® should be promptly switched to another anticoagulant agent. These decisions are based on the results of a randomized, phase II study to evaluate the safety and pharmacokinetics of oral dabigatran etexilate in patients after heart valve replacement (RE-ALIGN). **Pradaxa® is now contraindicated in patients with mechanical prosthetic heart valves requiring anticoagulant treatment.**

The RE-ALIGN study is a clinical trial conducted in Europe and was recently terminated because of increased thromboembolic events (strokes, heart attacks and blood clots) and bleeding in patients who were taking Pradaxa® than in patients who were taking anticoagulant warfarin. The RE-ALIGN study involved 249 patients who were undergoing surgical implantation of a mechanical heart valve and were treated with either 150 mg or 300 mg twice daily of Pradaxa® (160 patients) or a dose-adjusted warfarin (89 patients).[1]

In Saudi Arabia , Pradaxa® is approved to prevent venous thromboembolic events in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery and to prevent stroke and systemic embolism in adult patients with Non-Valvular Atrial Fibrillation [NVAF]. **However, Pradaxa ® is not approved as an anticoagulant for patients with prosthetic heart valves.**

In the meantime, SFDA is reviewing all data on this safety concern and will release the results of this review when it finished. SFDA advises all healthcare professionals **NOT** to use Pradaxa® in patients with mechanical prosthetic heart valves. All physicians who have patients with mechanical prosthetic heart valves and they are currently using Pradaxa® should promptly switch them to another anticoagulant agent. All healthcare professionals should be aware of the increased risk of thromboembolic and bleeding events associated with Pradaxa® use in patients with mechanical prosthetic heart valves.

Report Adverse Drug Reactions (ADRs) to the Saudi FDA

The SFDA urges both healthcare professionals and patients to report ADRs resulted from using such a medication and other medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance and Drug Safety Center (NPC)
Saudi Food and Drug Authority-Drug sector
3292 Northern Ring Road
Al Nafal District
Riyadh 13312 – 6288
Kingdom of Saudi Arabia
Toll Free: 8002490000
Tel: 012038222 ext. 2354, 2317
Fax: 012057662
Email: NPC.Drug@sfda.gov.sa
Website: www.sfda.gov.sa/NPC

References

1.Van de Werf, F, Brueckman M, Connolly SJ, et al. A comparison of dabigatran etexilate with warfarin in patients with mechanical heart valves: the randomized, phase II study to evaluate the safety and pharmacokinetics of oral dabigatran etexilate in patients after heart valve replacement (RE-ALIGN). Am Heart J 2012; 163:931-937.e1.