SFDA
Safety Communication

[09/JUN/2020]

Switching between Warfarin Brands and The Importance of Close Monitoring of INR

The Saudi Food and Drug Authority (SFDA) is issuing this safety communication to aware healthcare professionals about the importance of close monitoring of international normalized ratio (INR) in patients who are taking warfarin brands and switching to different brands of the drug.

Warfarin is a vitamin K antagonist used as oral anticoagulant. It is indicated for the prevention and treatment of venous thrombosis and its extension, pulmonary embolism, thromboembolic complications associated with atrial fibrillation, and/or cardiac valve replacement. For each indication, maintaining the target INR is the primary concern of warfarin safety and efficacy.

Warfarin can cause significant bleeding if not appropriately monitored. Bleeding is more likely to occur during the starting period and with a higher dose. When warfarin started, the INR should be determined daily or on alternate days in the early days of treatment. Once the INR has stabilized in the target range, the INR can be determined at longer intervals.

Moreover, INR should be monitored more frequently in high-risk patients, such as elderly patients, and patients with high-intensity anticoagulation (INR >4.0) or with highly variable INRs. Besides, patients with a history of gastrointestinal bleeding, hypertension, cerebrovascular disease, severe heart disease, malignancy, renal insufficiency, and patients using concomitant drugs.

There are currently three brands of Warfarin registered in Saudi Arabia [Coumadin® (by Bristol-Myers Squibb), Warfarin Sodium® (by Ivax Pharmaceuticals) and Coufatex® (by Apotex Inc.)].

The SFDA recommends that once the patient starts one of any warfarin brands to continue on the same brand as possible. In case of a shortage of any brands of warfarin, and then switching to different warfarin brand is required, the patient should be closely monitored with performing frequent INR testing to ensure adequate control for the INR. In addition, the patients should be advised about any changes in the warfarin brand prescribed and the need for additional INR monitoring. Moreover, the patients should be advised with the following instructions to minimize the risk of bleeding:

1. Strictly adhere to the prescribed dosage schedule. Do not take or discontinue any other drugs and herbal products without consulting your physician.

2. Notify physician immediately if any unusual bleeding or symptoms occur. Signs and symptoms of bleeding include pain, swelling or discomfort, prolonged bleeding from cuts, increased menstrual flow or vaginal bleeding, nosebleeds, bleeding of gums from brushing, unusual bleeding or bruising, red or dark brown urine, red or tar black stools, headache, dizziness, or weakness.
3. Regular visits to the physician or clinic are needed to monitor their therapy.
4. If the prescribed dose of warfarin is missed, take the dose as soon as possible on the same day but do not take a double dose of warfarin on the next day to make up for missed doses.
5. Contact their physician in case of pregnancy and breast-feeding.
6. Eat a normal, balanced diet to maintain a consistent intake of vitamin K. Avoid drastic changes in dietary habits, such as eating large amounts of leafy, green vegetables.
7. Avoid any activity or sport that may result in traumatic injury.
8. Contact physician to report any serious illness, such as severe diarrhea, infection or fever.
9. Be aware that if therapy with warfarin is discontinued, the anticoagulant effects of warfarin might persist for about 2 to 5 days.
10. Carry identification stating that they are taking warfarin if possible.
11. Tell their physician if they fall often as this may increase their risk for complications.
12. To avoid overdose, be aware that warfarin has different trade names in the Saudi market, and do not use them concomitantly.

Finally, SFDA advises the healthcare professionals to carefullyread the product information in the summary of product characteristics of warfarin, in particular, the safety information part before prescribing this medication.

The SFDA urges healthcare professionals and patients to report Adverse Drug Events (side effects) via any of the following contact information:

National Pharmacovigilance Center (NPC)
Saudi Food and Drug Authority - Drug sector
Centralized number: 19999
4904 Northern ring branch rd.- Hitteen District
Email: npc.drug@sfda.gov.sa
Riyadh 13513 - 7148
Webpage: http://ade.sfda.gov.sa
Kingdom of Saudi Arabia