SFDA
Safety communication

[15 September 2021]

The SFDA Requests Removing Pregnancy Contraindication for Statins

The Saudi Food & Drug Authority (SFDA) would like to notify healthcare professionals about removal of pregnancy contraindication for statins.

Statins are class of medicines that are mainly used to lower cholesterol levels in the blood, by inhibiting of the hydroxymethylglutaryl-CoA reductase enzyme. SFDA has approved Atorvastatin, Fluvastatin, Rosuvastatin, Pravastatin, Pitavastatin, and Simvastatin to decrease total cholesterol, low-density lipoprotein (LDL), and triglyceride concentrations and to increase high-density lipoprotein (HDL) concentrations.

The SFDA requests removal of pregnancy contraindication for registered statins from the marketing authorization holders (MAHs) in Saudi Arabia to allow the use of statins in very high-risk pregnant patients, since the benefits of statins might include prevention of serious or potentially fatal events in a small group of very high-risk pregnant women. This decision allows health care professionals to consider the benefits and risks profile of statins in pregnant women especially for patients at very high risk of heart attack or stroke such as patients with homozygous familial hypercholesterolemia and patients with history of heart attack or stroke. However, female patients should stop statins when they become pregnant unless they received advice from their physicians to continue on the medication. The benefits of statin therapy during pregnancy should be assessed individually for each patient by their physicians.

SFDA advises healthcare professionals to discontinue statin therapy in pregnant patients unless they consider the benefits of the statin therapy outweigh the risks. Also, SFDA advises healthcare professionals to instruct patients who are taking statin therapy to seek medical advice if they become pregnant or are planning to be pregnant, to allow making individual judgments regarding the benefits and risks of the use of statin therapy.

The SFDA has already requested to update the Summary Product Characteristics (SPC) and Patient information leaflet (PIL) of registered statins from the MAHs to reflect this new information.

Call for reporting:

The SFDA urges both healthcare professionals and patients to report ADRs related to the use of any medication to:

The National Pharmacovigilance Centre (NPC):

SFDA Call Center: 19999

E-mail: npc.drug@sfda.gov.sa Website:

https://ade.sfda.gov.sa