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Drug Safety Communication: FDA Requests Removal of Pregnancy Contraindication for Statins

Statins are a class of prescription medications that act by inhibiting 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase, an enzyme in the liver that is responsible for making cholesterol. Statins are commonly used for preventing and treating the build-up of fats, cholesterol, and other substances in and on the artery walls (atherosclerosis) and have been shown to reduce the incidence of heart attacks, strokes, and death. On July 20, 2021, the U.S. Food and Drug Administration (FDA) announced it is requesting removal of its strongest warning against using cholesterol-lowering statin medicines in pregnant patients.

Despite this change, the FDA still recommends that most patients stop statins once they learn they are pregnant. In addition, patients should not breastfeed when taking a statin because the medicine may pass into breast milk and pose a risk to the baby. Although many patients should be able to stop statins temporarily until breastfeeding ends, patients who are at high risk of heart attack or stroke who require statins after giving birth should not breastfeed and should use alternatives such as infant formula.

Statins are safe to prescribe in patients who are not pregnant but may become pregnant and unintended exposure to statins in early pregnancy is unlikely to cause harm to the developing fetus. Published data from prospective and retrospective observational cohort studies with statin use in pregnant women are insufficient to determine if there is a drug-associated risk of miscarriage.

To minimize risk to patients, health care professionals should consider the following actions:

- Discontinue statin therapy in most pregnant patients, while also considering the ongoing therapeutic needs of the individual patient, especially patients at very high risk of cardiovascular events during pregnancy, such as patients with homozygous familial hypercholesterolemia or those with established cardiovascular disease.
- Discuss with patients whether they may discontinue statins temporarily while breastfeeding. Advise those who require a statin because of their cardiovascular risk that breastfeeding is not recommended because the medicine may pass into breast milk.
- Report side effects involving statins or other medications to the FDA MedWatch program.

To read the full safety announcement, which includes a summary of the studies reviewed by the FDA, refer to the article ["FDA requests removal of strongest warning against using cholesterol-lowering statins during pregnancy; still advises most pregnant patients should stop taking statins"](#) found on the [Drug Safety and Availability](#) page of the FDA website.