

Statins – Removal of contraindication

- On July 20, 2021, the [FDA announced](#) the request to remove the contraindication against using cholesterol-lowering statin medicines in pregnant patients.
 - A contraindication is the FDA’s strongest warning and is only added when a medicine should not be used because the risk clearly outweighs any possible benefit.
- Because the benefits of statins may include prevention of serious or potentially fatal events in a small group of very high-risk pregnant patients, contraindicating these drugs in all pregnant women is not appropriate.
- The FDA expects removing the contraindication will enable health care professionals and patients to make individual decisions about benefit and risk, especially for those at very high risk of heart attack or stroke. This includes patients with homozygous familial hypercholesterolemia and those who have previously had a heart attack or stroke.
- Statins are a class of prescription medicines that have been used for decades to lower low-density lipoprotein (LDL-C or “bad”) cholesterol in the blood.
 - Medicines in the statin class include atorvastatin, fluvastatin, lovastatin, pitavastatin, pravastatin, rosuvastatin, and simvastatin. They are marketed as single-ingredient products and in combination with other medicines. They are available as brand and generic products.
- Patients taking statins should notify their health care professionals if they become pregnant or suspect they are pregnant. A health care professional will be able to advise whether patients should stop taking the medicine during pregnancy and whether statins should be stopped temporarily while breastfeeding. 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.
- Health care professionals should discontinue statin therapy in most pregnant patients, or they can consider the ongoing therapeutic needs of the individual patient, particularly those at very high risk for cardiovascular events during pregnancy.
- Because of the chronic nature of cardiovascular disease, treatment of hyperlipidemia is not generally necessary during pregnancy. Healthcare provider should 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.
- The safety update is based on the FDA’s review of the medical literature.
 - There is insufficient evidence to determine whether statins can cause miscarriage.
 - Observational studies have not identified an increase in birth defects associated with statin use during pregnancy after adjusting for potential confounders.
 - Animal data suggest limited potential for statins to cause malformations, and limited potential to affect the developing nervous system or cause embryofetal death.

- Statins decrease the synthesis of cholesterol and possibly other biologically active substances derived from cholesterol. Therefore, statins may cause fetal harm when administered to pregnant patients.



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