

Pharmacovigilance Drug Safety Communication

FDA requests the removal of pregnancy as a contraindication against using statins; statin use may be considered in very-high risk pregnant patients. **Most patients should stop statins if they are pregnant.**

What is Changing?

The FDA is requesting the removal of pregnancy as a contraindication against using statins.

What are the key points?

- Most patients should stop statins once they learn that they are pregnant.
 - Temporary discontinuation of lipid lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hyperlipidemia for most patients.
 - 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.
- The benefits of statin therapy may outweigh the risks in a small group of very high-risk pregnant patients (e.g., patients with homozygous familial hypercholesterolemia and those who have previously had a heart attack or stroke).
- Patients should not breastfeed when taking a statin.
 - Many can stop statins temporarily until breastfeeding ends. However, patients requiring ongoing statin treatment should not breastfeed and instead use infant formula or other alternatives.

Why is FDA making this change?

Multiple randomized trials and meta-analyses have demonstrated the benefit of statin therapy on the prevention of cardiovascular events. Data from published observational studies of statin use in pregnant women have not identified a drug-associated risk of major birth defects when controlling for other risks such as diabetes and are insufficient to determine if there is a drug-associated risk of miscarriage. 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.

The complete Drug Safety Communication can be viewed on the [FDA website](#).

To help the FDA track safety issues with statins and other medications, please report adverse events to the MedWatch program as recommended in the [Indian Health Manual](#). Instructions for reporting can be found online at the [NPTC Pharmacovigilance website](#).