

FDA approves label changes for use of general anesthetic and sedation drugs in young children

This is an update to the [FDA Drug Safety Communication: FDA review results in new warnings about using general anesthetics and sedation drugs in young children and pregnant women](#) issued on December 14, 2016.

Safety Announcement

[4-27-2017] The U.S. Food and Drug Administration (FDA) is notifying the public that we have approved previously announced label changes regarding the use of general anesthetic and sedation medicines in children younger than 3 years. These changes include:

- A new Warning stating that exposure to these medicines for lengthy periods of time or over multiple surgeries or procedures may negatively affect brain development in children younger than 3 years.
- Addition of information to the sections of the labels about pregnancy and pediatric use to describe studies in young animals and pregnant animals that showed exposure to general anesthetic and sedation drugs for more than 3 hours can cause widespread loss of nerve cells in the developing brain; and studies in young animals suggested these changes resulted in long-term negative effects on the animals' behavior or learning.

General anesthetic and sedation drugs are necessary for patients, including young children and pregnant women, who require surgery or other painful and stressful procedures. In the U.S., surgeries during the third trimester of pregnancy requiring general anesthesia are performed only when medically necessary and rarely last longer than 3 hours. We are advising that in these situations, pregnant women should not delay or avoid surgeries or procedures during pregnancy, as doing so can negatively affect themselves and their infants.

Similarly, surgeries or procedures in children younger than 3 years should not be delayed or avoided when medically necessary. Consideration should be given to delaying potentially elective surgery in young children where medically appropriate.

Parents, caregivers, and pregnant women should talk to their health care professionals if they have any questions or concerns about general anesthesia and sedation drugs.

Health care professionals should continue to follow their usual practices of patient counseling including discussing the benefits and risks of surgeries or procedures that require general anesthesia and sedation drugs.

We will continue to monitor the use of these drugs in children and will update the public if additional information becomes available.

We urge patients and health care professionals to report side effects involving general anesthetics and sedation drugs or other medicines to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page.

Related Information

[Pediatric Anesthesia](#)

[SmartTots \(Strategies for Mitigating Anesthesia-Related neuroToxicity in Tots\)](#)

[The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective](#)

[Think It Through: Managing the Benefits and Risks of Medicines](#)