Major Changes to Cytotec Labeling

- Revises the contraindication and precaution that Cytotec should not be used in women who are pregnant by stating that the contraindication is for pregnant women who are using Cytotec to reduce the risk of non-steroidal anti-inflammatory drug (NSAID)-induced stomach ulcers.

  Rationale: The drug has a recognized use by obstetricians and gynecologists (OB-Gyns) to induce labor, delivery, and is part of the FDA approved regimen for use with mifepristone to induce abortion in pregnancies of 49 days or less. The contraindication now refers to the drug's approved indication, for reducing the risk of NSAID-induced gastric ulcers.

- Creates a new labor and delivery section of the labeling and provides safety information related to those uses.

  Rationale: 21 CFR 201.57(f)(7) requires labeling to include drug effect information if a drug has a recognized use during labor or delivery, whether or not the use is stated in the indications section of the labeling.

- Provides new information that uterine rupture, an adverse event reported with Cytotec, is associated with risk factors, such as later trimester pregnancies, higher doses of the drug, including the manufactured 100 mcg tablets, prior Cesarean delivery or uterine surgery, and having had five or more previous pregnancies.

  Rationale: Risk factors allow physicians to identify patients who may be at greater risk for these adverse events. This information may guide safer use of the drug.

  5/21/02