

# MISOPROSTOL - Major labelling changes

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USA. Changes to misoprostol (Cytotec) labelling have been posted on the US FDA web site.

- The statement that misoprostol (Cytotec) is contraindicated in pregnant women has been removed from the product label. This change is based on the fact that the drug is frequently used to induce labour and delivery and the fact that it is part of the FDA approved regimen for use with mifepristone to induce abortion in pregnancies of 49 days or less.
- The label clarifies that the contraindication in pregnant women concerns those who are using misoprostol to reduce the risk of non-steroidal anti-inflammatory drug-induced stomach ulcers. This does not contraindicate off-label use of misoprostol.
- A Labour and Delivery section has been added that contains safety information regarding the use of misoprostol in these areas.
- The label provides new information that uterine rupture, an adverse event reported with misoprostol (Cytotec) is associated with risk factors such as later trimester pregnancies, higher doses of the drug, prior Caesarean delivery or uterine surgery and having had five or more previous pregnancies.

Reference:

Summary of labelling changes by FDA, 17 Apr 2002.

Available from URL: <http://www.fda.gov>