

 **U.S. Food and Drug Administration**  Department of Health and Human Services

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## Patient Information Sheet Misoprostol (marketed as Cytotec)

This is a summary of the most important information about misoprostol. For details, talk to your healthcare professional.

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### **FDA ALERT: – Risks of Use in Labor and Delivery**

**This Patient Information Sheet is for pregnant women who may receive misoprostol to soften their cervix or induce contractions to begin labor. Misoprostol is sometimes used to decrease blood loss after delivery of a baby. These uses are not approved by the FDA. No company has sent the FDA scientific proof that misoprostol is safe and effective for these uses.**

**There can be rare but serious serious side effects, including a torn uterus (womb), when misoprostol is used for labor and delivery. A torn uterus may result in severe bleeding, having the uterus removed (hysterectomy), and death of the mother or baby. These side effects are more likely in women who have had previous uterine surgery, a previous Cesarean delivery (C-section), or several previous births.**

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### **What Is Misoprostol?**

- Misoprostol is a drug approved by the FDA to decrease the chance of getting stomach ulcers caused by taking certain arthritis or pain medicines.
- Misoprostol also has effects on the womb and cervix.

### **Who Should Not Take Misoprostol for Labor and Delivery?**

- Pregnant women who have had a previous C-section or removal of fibroid tumors in the wall of the uterus should not receive misoprostol for softening the cervix or inducing contractions to begin labor.

### **How is Misoprostol Used?**

- Misoprostol comes as a tablet. Sometimes the tablets are split, and you will be given only a piece of a tablet. You may be asked to take misoprostol by mouth, or it may be placed in your vagina or rectum.

### **Is There Anything Else I Need To Know?**

- There are other drugs to soften the cervix or induce labor or contractions that are approved by the FDA. There also can be similar serious side effects from these drugs. You may need to have your cervix softened or contractions induced for your health or your baby's health. Talk to your doctor about all your options and what is best for you.

Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570  
[Druginfo@cdcr.fda.gov](mailto:Druginfo@cdcr.fda.gov)

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