INSTRUCTIONS FOR USE

ABORTION INDUCTION WITH MISOPROSTOL IN PREGNANCIES THROUGH 9 WEEKS LMP

BACKGROUND

Misoprostol is a prostaglandin analog widely marketed as Cytotec®. Cytotec® is registered for use to prevent gastric ulcers resulting from chronic administration of nonsteroidal anti-inflammatory drugs (NSAIDs). As Cytotec® also induces uterine contractions, it is often used off-label for pregnancy termination. Studies have demonstrated that misoprostol can be used to terminate pregnancies of any gestation. This information is presented for the guidance of trained medical professionals.

INDICATION AND USAGE

Effective regimens, their course, and success and complication rates depend on the length of gestation. The following information applies to pregnancies estimated to be 9 completed weeks (63 days) LMP or less. Use of misoprostol for pregnancy termination of gestations through 9 weeks LMP has a success rate of 85-90%. It is important to know the duration of the pregnancy, for example as estimated by the last normal menstrual period, in order to determine if it is appropriate for the woman to use this method.

CONTRAINDICATIONS

– Confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass

– IUD in place (remove IUD before administering misoprostol)

– History of allergy to misoprostol or other prostaglandin

PRECAUTIONS

1. TERATOGENIC EFFECTS IN LIVE BIRTHS FOLLOWING FAILED ABORTION WITH MISOPROSTOL

According to animal model evidence, only one study involving rats has shown a teratogenic effect of misoprostol.

Sixty-nine cases of live births exhibiting anomalies after misoprostol exposure *in utero* have been reported. A review of these case reports reveals that the majority of the reported anomalies can be classified as pertaining to the central nervous system and the upper and lower limbs. The most frequent anomalies identified among all cases are equinovarus (clubfoot), followed by anomalies of cranial nerves VII, VI, V, and XII, and agenesis (absence) of the fingers.

Three case-control studies conducted in human populations have consistently shown a higher prevalence of anomalies among misoprostol-exposed infants. However, the absolute risk of teratogenicity with misoprostol exposure appears low, on the order of 10 per 1000 exposed fetuses. In population-based registries, the observed incidence of anomalies does not appear to be high, even when misoprostol exposure is relatively frequent in the population.

2. NURSING MOTHERS

Misoprostol is rapidly metabolized throughout the body. It is not known if the active metabolite (misoprostol acid or misoprostol) is excreted in human milk, although almost all substances found in maternal serum are excreted in breast milk. Discarding breast milk for 24 hours after misoprostol administration may be prudent to avoid the potential occurrence of abdominal cramps or diarrhea among breast fed infants.

3. GESTATIONAL AGE BEYOND 9 COMPLETED WEEKS LMP

Caution is recommended when administering misoprostol for abortions beyond 9 completed weeks LMP. There is insufficient evidence to recommend a regimen of misoprostol for late first trimester abortion induction. The regimen described here is inappropriate beyond the first trimester; the doses indicated here are too high for use later in gestation (see Notes).

Effects and Side Effects

Prolonged or serious effects and side effects are rare.

1. Bleeding

Bleeding often starts within the first day, generally within an hour after taking misoprostol. Bleeding typically lasts 7 to 10 days with additional days of spotting that can last until the next menstrual period. Return to menses usually occurs 4 to 6 weeks after misoprostol administration. It is important to understand that bleeding alone does not indicate a successful abortion.

The woman should be instructed to contact the provider if any of the following occur: (1) if she soaks more than two maxi sanitary pads an hour for more than two consecutive hours, (2) if she stops bleeding and subsequently experiences a sudden onset of extremely heavy bleeding two weeks or longer after taking misoprostol, (3) if she has bled continuously for several weeks or begins to feel dizzy or light-headed, or (4) if no or scant bleeding has occurred by 7 days after misoprostol administration.

2. Cramping

Cramping usually starts within the first day and may begin as early as 30 minutes after misoprostol administration. The pain may be much stronger than that experienced during a regular period. Nonsteroidal anti-inflammatory drugs (NSAIDs) or other analgesia can be used for pain relief without affecting success of the method.

3. Chills and/or fever

Chills are common side effects of misoprostol but are transient. Fever is less common and does not necessarily indicate infection. If fever or chills persist beyond 24 hours after taking misoprostol, the woman may have an infection and should seek medical attention. An antipyretic can be used for relief of fever, if needed.

4. Nausea and vomiting

Nausea and vomiting may occur and will resolve 2 to 6 hours after taking misoprostol. An antiemetic can be used if needed.

5. Diarrhea

Diarrhea may also occur following administration of misoprostol but should disappear within a day.

Dosage and Administration

The recommended regimen for abortion induction with misoprostol in pregnancies through 9 weeks LMP is **800 mcg vaginal misoprostol, repeated after 24 hours (2 x 800 mcg)**.

Evidence indicates that wetting the tablets with a few drops of water after vaginal insertion is likely to increase success with the method.

Notes:

- Misoprostol probably also works well when placed between the cheek and gum (buccally) or under the tongue (sublingually).
- Currently, there is insufficient evidence to recommend a specific regimen of misoprostol for late first trimester induction. As gestation increases and the uterus becomes more sensitive to misoprostol, the dose necessary to effect expulsion will decrease. However, with increasing gestation, both the time required to expel the pregnancy and the expected blood loss will be increased.

Suggested Citation:
Consensus Statement: Instructions for Use – Abortion Induction with Misoprostol in Pregnancies through 9 Weeks LMP. Expert Meeting on Misoprostol sponsored by Reproductive Health Technologies Project and Gynuity Health Projects. July 28, 2003. Washington DC.

For a reference list of literature supporting this document or for more information, refer to www.gynuity.org or www.rhtp.org.

Revised: 8/31/2004