

PERI-GRAM

OBSTETRIC INFO/NEWS

What is Crinone?	Who needs it?	Dosage	Advantages
<i>A formulation of vaginal micronized progesterone, suspended in a polymer gel rather than in oil.</i>	<i>Vaginal progesterone reduces the risk of preterm birth in women with a short cervix, singleton pregnancy</i>	<i>Crinone 8% has 90 mg of progesterone. Dose for PTB prevention is "One applicator daily" usually in morning</i>	<i>Proven for PTB prevention. Synthetic polymer gel avoids oily vaginal discharge.</i>

CRINONE ON FORMULARY AT GSH

Crinone 8% (vaginal progesterone) is now on the formulary at Good Samaritan. It is indicated to prevent preterm birth (PTB) in singleton pregnancy complicated by short cervix. Crinone gel is the precise formulation shown to reduce early PTB in a placebo-controlled trial (see side-bar).

Vaginal micronized progesterone reduces the risk of early PTB in women with a singleton pregnancy who are found to have a short cervix. With twin pregnancy, benefit of progesterone has *not* been proven. Several brands of FDA-approved micronized progesterone are available:

- **CRINONE 8%:** Progesterone in a synthetic polymer gel. This precise formulation was used in the Hassan trial. Thus, there is good Level 1 evidence supporting its use with short cervix. Crinone is identical to PROCHIEVE, a different brand-name from the same manufacturer. Prochieve is not currently available in the USA, but this may change during 2012.
- **PROMETRIUM:** Progesterone in peanut oil. FDA-approved labeling is for *oral* use. There is no data to support bioavailability with vaginal use or demonstrating efficacy to prevent PTB. Oily discharge is typical when used vaginally. Contraindicated with peanut allergy.
- **ENDOMETRIN:** Progesterone vaginal tablets. There is no data demonstrating efficacy of this brand for preterm birth prevention.
- **COMPOUNDED PROGESTERONE:** There is no reason to use these "home-brew" forms of micronized progesterone when three FDA-approved forms are readily available.

Evidence

In a placebo-controlled trial, Hassan et al showed that Crinone 90 mg daily reduced the risk of early preterm birth in women with a cervical length of 10-20 mm found on routine ultrasound screen (Ultrasound Obstet Gynecol 2011;38:18-31). Rate of PTB < 33 wks was 11% with Crinone versus 20% with placebo. Neonatal morbidity was also reduced.

In an earlier trial, Fonseca et al showed a similar effect using a 200 mg progesterone capsule QHS in women with cervical length 15 mm or less. (New Engl J Med 2007;357:462-9). Rate of PTB < 34 wks was 21% with progesterone versus 36% with placebo. The capsules used in this study were a brand not available in the USA.



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