



PROGESTERONE IN EARLY PREGNANCY BLEEDING

The effectiveness of progesterone to prevent miscarriage in women with early pregnancy bleeding: A randomised placebo-controlled trial

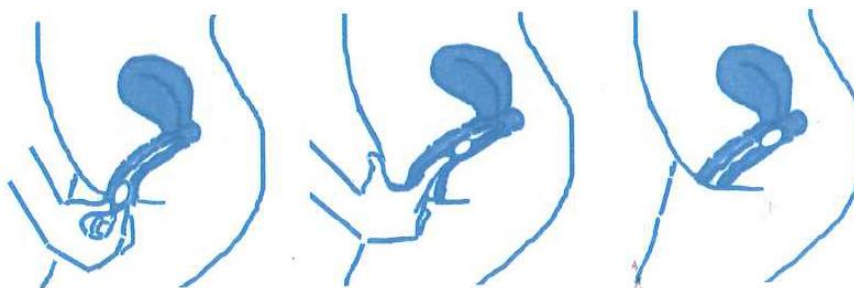
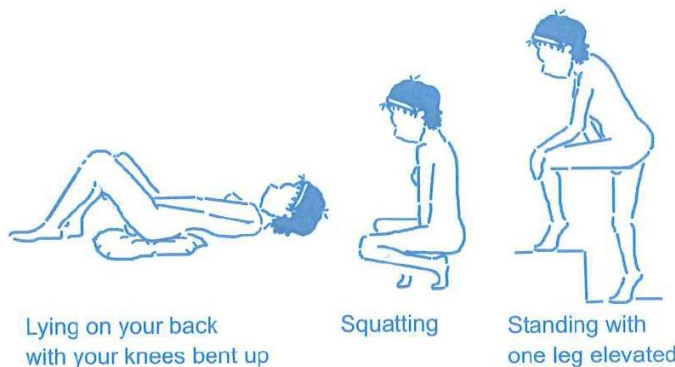
INSTRUCTIONS FOR TAKING VAGINAL CAPSULES

FOR THE PRISM STUDY

- ✓ The capsules used for treatment in the PRISM trial are soft and white, each about the size of a baked bean.
- ✓ The active substance contained in the trial capsule is progesterone at a dose of 200mg. The other ingredients are sunflower oil and soybean lecithin. The other ingredients in the capsule shell are gelatin, glycerol and titanium dioxide.
- ✓ We recommend that the capsules are inserted vaginally, however if there is a good medical reason the capsules can be used as suppositories (inserted into the rectum).
- ✓ You should **NOT** take the capsules by mouth.
- ✓ Two capsules, inserted one by one, should be used each morning and evening until you reach 16 weeks of pregnancy. The first dose should be taken in the evening of the day that you receive your treatment pack.

INSTRUCTIONS FOR INSERTION

1. Wash your hands thoroughly.
2. Remove the capsule from its packaging.
3. Choose the best comfortable positions for vaginal (or rectal) insertion, such as:
 - Lying on your back with your knees bent up
 - Squatting
 - Standing with one leg elevated
4. Gently insert the capsule into the vagina (or rectum) with your fingers.



- ✓ If you forget to take your capsules on any occasion, two capsules should be taken as soon as you remember. However, if it is nearly time for the next dose, please skip the missed dose.
- ✓ **DO NOT** use a double dose to make up for a forgotten dose.
- ✓ If you think you have used too much of the treatment, or if you experience any side effects, you should seek medical advice.
- ✓ Keep capsules in the original blister pack and in the original outer carton supplied.
- ✓ As with all other medications, this medication should not be shared with anyone. The capsules have been prescribed for your personal use only.
- ✓ When you reach 16 weeks of pregnancy, you should discontinue taking the capsules.
- ✓ ALL completed, partially used and unused treatment packs should be returned to your local research team at your next hospital visit.
- ✓ If you are unable to return your treatment pack, whether empty or not, please contact your research team by telephone or email, who will be able to assist you.
- ✓ Please keep your capsules away from extremes of temperature and out of the reach of children.
- ✓ If you have any questions about the capsules please contact the trial team.