

Clinic Uses: Pre-Seed® is also used to lubricate vaginal tissues to facilitate entry of diagnostic or therapeutic devices, including those used in fertility interventions. Prior to insertion, Pre-Seed® can be applied directly to the device or deposited intravaginally using the applicator. Use of Pre-Seed® is appropriate for use in fertility interventions, including:

- Intrauterine insemination
- In vitro fertilization
- Transvaginal oocyte collection
- Embryo transfer

Remove seal from tube before initial use. If sterilized product is desired, please follow the instructions for sterilization. Enclosed applicators are not sterile and should not be used when sterile product is desired.

With Applicator: Prior to insertion of the instrument, fill one of the enclosed applicators with the desired amount of Pre-Seed® and insert into the vagina. **Do not store Pre-Seed® in applicator for more than 30 minutes prior to use.**

Without Applicator: Apply desired amount of Pre-Seed® to instrument and/or genital area. Vary amount to achieve desired lubrication.

Quality Assurance: Each lot of Pre-Seed® is tested to ensure the following:

Test	Specification
pH	7.0 – 7.4
Osmolality (ion concentration)	260mOsm – 370mOsm
Endotoxin by LAL methodology	Reported
Biocompatibility by mouse embryo assay	1-Cell MEA > 80% expanded blastocysts at 96 hours
Biocompatibility by sperm motility	Sperm motility after 30-minute exposure to 10% lubricant solution equal to 80% or more than seen for sperm with no lubricant present.

Results of the mouse embryo assay (MEA), endotoxin testing (LAL) and sperm motility assay are reported on a lot-specific Certificate of Analysis, which is available upon request.

Validated Instructions for Sterilization: Tube

1. Moist heat/steam sterilization is the preferred and recommended method for Pre-Seed®.
2. Using aseptic technique, transfer desired quantity of lubricant to a steam-compatible container (e.g., conical centrifuge tube of polypropylene or borosilicate glass). Do not fill the container to more than 75% of capacity to allow room for expansion. Place cap on container, but do not tighten. The cap must be loose to ensure proper sterilization and to prevent damage to the container.

3. The recommended steam sterilization parameters are as follows:

Sterilizer Type	Temperature	Full Cycle Time
Gravity	121°C (250°F)	30 minutes

4. Remove the container from the autoclave. Once the container has cooled, tighten the cap.
5. Regularly test the efficacy of steam autoclaves as recommended by the equipment manufacturer or local regulations. Sterilizer manufacturer recommendations for operation and load configuration should be followed explicitly.

Important: The applicator provided in this package is not sterile. If intravaginal application of sterilized lubricant (as described above) is desired, a sterile instrument should be utilized.

Ingredients: Purified Water, Hydroxyethylcellulose, Pluronic, Sodium Chloride, Sodium Phosphate, Carbomer, Methylparaben, Sodium Hydroxide, Arabinogalactan, Potassium Phosphate, Propylparaben

Questions & Information: Visit us at preseed.com for detailed product information and to review clinical study data.



pre~seed.
personal lubricant

“fertility~friendly”™

Almost every woman will experience vaginal dryness sometime during her life, which can cause discomfort or irritation during sexual intimacy. For women who are trying to conceive (TTC), the frequency of vaginal dryness can increase as couples transition from lovemaking to “baby-making,” with scheduled intercourse around the woman’s fertile time each month. Unfortunately, “everyday” lubricants can damage sperm and should not be used when you are ready to become pregnant.

Thankfully, Pre-Seed® personal lubricant relieves vaginal dryness without harming sperm. Its unique moisture is balanced to match fertile cervical mucus, which is normally produced by women around the time of ovulation. Pre-Seed® is deposited inside the vagina to supplement moisture and to enhance the ease and comfort of intimacy, while being safe to use when trying to conceive!



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Pre-Seed is manufactured in the USA for INGfertility®, Spokane, WA, USA.
www.preseed.com

Applicators are manufactured by SRC Medical, Hanover, MA, USA.

Distributed in Canada by TRIMEDIC Supply Network Ltd. info@trimedinc.com

Patents: Canada # 2235069,
US # 6,593,309/ 6,140,121

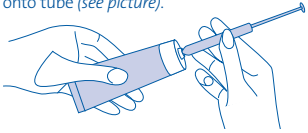
PT 7-304 VER 09.10

40g Tube with 9 single-use applicators

Personal Uses: Pre-Seed® supplements the body's own natural lubricating fluids to moisturize, relieve friction and to enhance the ease and comfort of intimate sexual activity. Pre-Seed® is safe for use by couples who are trying to conceive and may be applied to vaginal or penile tissues for lubrication and moisturization purposes. It is compatible with latex and polyurethane condoms.

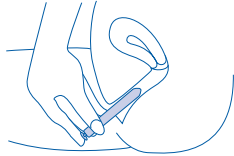
Directions for Using Pre-Seed® with Disposable Applicators:

1. Remove seal from tube before initial use.
2. Pre-Seed® can be applied up to 15 minutes prior to intercourse. Applying it before you begin making love allows the moisture to disperse throughout the vagina and allows more spontaneity for you as a couple.
3. Attach the applicator to the Pre-Seed® tube by twisting the end of the applicator firmly onto tube (see picture).



4. Gently squeeze the Pre-Seed® into the applicator, and continue squeezing until the applicator is full or the desired amount is present in the applicator. Most women will choose the 3 gm fill line to meet their product needs. Separate the applicator from the tube. Be sure and keep the open end of the applicator upright so product is not lost. **After each use, replace the cap and roll up the tube from the bottom.** Do not leave Pre-Seed® uncapped between uses.
5. **Do not store Pre-Seed® in the applicator for more than 30 minutes prior to use.** This means if you draw Pre-Seed® into the applicator but do not insert it intravaginally within 30 minutes, the unused Pre-Seed® needs to be discarded and the applicator disposed of.

6. To apply Pre-Seed®, gently insert the applicator deep into the vagina. This can be done while standing, lying down or sitting (such as on the toilet).
7. Holding the barrel of the applicator, slowly push the plunger all the way in to release the lubricant into the vagina (see picture).



8. Remove both parts of the applicator from the vagina.
9. In order to get the right amount of moisture for your body*, bear down slightly after depositing the product. This will expel any excess Pre-Seed® that your body doesn't need. If desired, use a tissue to lightly wipe off any extra product that is on the vulva.
10. Discard applicator following use. **DO NOT REUSE APPLICATORS.**

** If this application method doesn't provide enough moisture, we suggest you apply Pre-Seed® inside the vagina (as shown) while lying down in bed, IMMEDIATELY before intercourse. You may also want to squeeze a small amount of Pre-Seed® from the tube onto your fingertips, and apply directly to external genitalia. If this application method provides too much moisture for you, apply the product earlier before intercourse (e.g., up to an hour), or apply fewer grams of product. Also, be sure to bear down to expel extra Pre-Seed® after application, and wipe off excess product from the vulvar area.*

Directions for Using Pre-Seed® Externally:

Squeeze a small amount of Pre-Seed® (size of a quarter or teaspoon) onto your fingertips and apply to genital area. Vary amount to achieve desired lubrication. Pre-Seed® mild ingredients require you to apply a bit more Pre-Seed® initially than you might with other products, in order to saturate the skin and provide longer lasting lubrication.

Directions for Using Pre-Seed® with Condoms:

For use with condoms, apply Pre-Seed® directly from the tube. Add a small amount of Pre-Seed® to the penis prior to condom use followed by application to outer condom surface. For semen collection, only polyurethane condoms should be used.

Individuals Using Pre-Seed® While Trying to Conceive:

- Consult your physician if you have not become pregnant after 6 months of product use.

Warnings:

- Pre-Seed® is not a contraceptive. It does not harm sperm or interfere with their function.
- Keep out of reach of children.
- Do not use if quality seal on the tube is broken; instead, return entire contents to place of purchase.
- Pre-Seed® is extremely slippery; clean up any spills immediately.
- Do not use product if active infection or vaginal trauma is present.
- **DO NOT USE AFTER EXPIRATION DATE.** Expiration date can be found on the tube crimp and the outside of the carton (4-number year and 2-number month).

Caution: If application of Pre-Seed® causes irritation or discomfort, discontinue use of the product. If symptoms persist, contact your physician.

Important: The applicators are single use only. Dispose of each applicator after use by placing it in a trash receptacle. **DO NOT REUSE APPLICATOR.**

If additional lubrication is needed, use a new applicator or apply by hand.

Store at room temperature (15°C to 30°C).

No patient data are available regarding viable pregnancies or birth outcomes in patients using this product.

The Inventor:

I am a mother to five boys and a Sperm Physiologist with over 15 years of federal funding to study male infertility. During this work, I saw that fertility problems often impacted a couple's intimate relationship, leading to increased vaginal dryness. Although I knew lubricants harmed sperm, I hated telling couples that there was really nothing "safe" for them to use while trying to conceive. So I spent eight years developing Pre-Seed® to replenish a woman's moisture without harming sperm.



Pre-Seed® is uniquely formulated to share characteristics with fertile cervical mucus. Several independent studies presented at major medical meetings have shown Pre-Seed® benefit on sperm and embryo function. You can see these studies at preseed.com. Each lot of Pre-Seed® is also tested before it can be sold to confirm that it has the right "fertility-friendly" properties.

Pre-Seed® is the only lubricant allowed to say that it is "safe to use when trying to conceive." This is the result of years of testing, regulatory review and analysis by independent physicians and scientists. Trying-to-conceive couples can be a very vulnerable group and unfortunately there is a great deal of misinformation they can encounter. I am very proud of Pre-Seed® and the wonderful impact it has had on many couples' lives. I am grateful to the many users and healthcare professionals who have taken the time to write us about their experiences with Pre-Seed®. I hope you will go to preseed.com to read these stories, and view our information about trying to conceive in general at the FAQs page and blog. We would also love to hear from you about your TTC journey and experience with Pre-Seed® (info@preseed.com). It brings all of us at Pre-Seed® great joy!

Blessings! Joanna Ellington – PhD "Dr. E"