

Package Insert

Indications for Use

BabyDance Fertility Lubricant[™] is a personal lubricant for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. BabyDance Fertility Lubricant is compatible with sperm, oocytes, and embryos and can be used by trying to conceive couples. BabyDance Fertility Lubricant is compatible with natural rubber latex and polyurethane condoms.

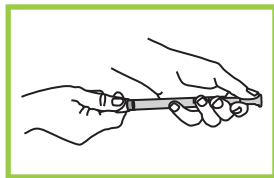
BabyDance Fertility Lubricant can be used to lubricate genital tissues and devices to facilitate use of diagnostic and therapeutic devices during fertility interventions and reproductive medicine.

Directions

To supplement natural lubrication, BabyDance is designed to be applied deep inside the vagina prior to intercourse. Most women apply the lubricant before intimacy begins, but it can be applied anytime prior to or during intercourse to enhance the comfort of intimacy. To best mimic a woman's natural secretions, apply BabyDance intravaginally, according to the following instructions:

1. Select one single-use tube from the carton. Remove the cap and puncture the protective seal with the cap point. Take one applicator out of its plastic wrap.
2. With the applicator plunger closed, twist the applicator onto the BabyDance tube.

3. Expel the BabyDance tube contents into the applicator **by squeezing on the tube**. For first-time use, we suggest you expel the entire tube content into the applicator. If this volume is too much during your intimacy, simply use a clean cloth to wipe off the vulvar area, and continue love-making. Then next time, fill the applicator with a smaller volume of BabyDance. BabyDance's unique myDose system – which provides single use tubes and applicators that can hold as much or as little lubricant as you need - allows YOU to choose the amount of product to moisturize and supplement natural lubrication.



4. BabyDance should be used immediately once the applicator is filled. Holding the applicator with the open end up, untwist the applicator from the small tube and keep it upright until BabyDance is applied inside the vagina.

5. While standing, sitting or lying down, use one hand to part the vulvar lips. Gently guide the applicator into the vagina with the other hand. If the applicator does not insert easily, try pulling back slightly and redirecting it more towards the back wall of the vagina. For easier insertion of the applicator into the vagina, use any lubricant remaining in the tube to lubricate the vulvar region.



6. Once the applicator has been inserted deep into the vagina, depress the plunger to deliver BabyDance. Then remove the applicator and discard it.

To apply BabyDance externally, squeeze the entire contents of the tube into your hand and apply to the vulvar area and/or your partner's penis.

Using BabyDance with Condoms

For use with non-lubricated latex or polyurethane condoms, apply BabyDance **directly from the tube**. For easier placement of the condom, squeeze a small amount of BabyDance onto your fingertips and apply to the penis prior to putting on the condom. Follow this with application of BabyDance to the outer condom surface.

Professional Use In The Clinic

BabyDance can be used to lubricate genital tissues and devices to facilitate use of diagnostic and therapeutic devices during fertility interventions and reproductive medicine. Prior to device insertion, BabyDance can be applied directly to the device from the tube; deposited intravaginally using the applicator; or applied to the penis for lubrication. **BabyDance and applicators are not sterile. This product should not be used if sterile product is required.**

Quality Assurance

Each lot of BabyDance Fertility Lubricant is tested to ensure the following:

Physical Specification/Test	Ranges/Specifications
Color/appearance	Opaque
Odor	Slight rose and sage odor
pH @ 25° C	6.8 to 7.2
Osmolality	260 to 370 mOsmo/kg
Apparent Viscosity	2000 to 14,000 cps
Total Aerobic Microbial Count (TAMC) per USP <61>	< 100 cfu/g
Total Yeast and Mold Count (TYMC) per USP <61>	< 10 cfu/g
Pathogens (<i>Pseudomonas aeruginosa</i> , <i>Escherichia Coli</i> , <i>Salmonella sp.</i> , <i>Candida albicans</i>) per USP <62>	Absent
Endotoxin by endotoxin methodology per USP <85>	≤ 0.5 EU/ml
Biocompatibility by Mouse Embryo Assay	Using 1-cell MEA exposed to 10% solution for 30 min. ≥ 80% expanded blastocysts at 96 hrs.
Biocompatibility by Sperm Motility	Sperm motility following 30 min. incubation with 10% diluted lubricant solution equals ≥ 80% of sperm in control medium

Results of the specification testing are reported on a lot specific Certificate of Analysis, which is available upon request.

Important

Do not remove applicator from outer wrapping until just before use. Once opened, use immediately. Discard the tube and applicator after each use. Tubes and applicators are single-use only. DO NOT REUSE. Store at 36-86° F (2-30° C).

Some women feel a warming sensation in the vagina when first using BabyDance. This sensation may be due to the pH balancing of vaginal tissues in preparation for ovulation and generally decreases with subsequent use.

Ingredients

Purified water, cetyl hydroxyethylcellulose, hypromellose, carbomer homopolymer type B, sodium phosphate, potassium phosphate, sodium chloride, raspberry-derived xylose, sodium hydroxide, phenethyl alcohol, caprylyl glycol, *Salvia sclarea* (clary sage)

Caution

If irritation occurs, discontinue product immediately. If irritation persists consult your health care provider.

Warnings

- BabyDance is not a contraceptive. ***BabyDance does not harm sperm.***
- Do not use if quality seal on the tube is broken; instead return BabyDance to the place of purchase.
- Do not use BabyDance if active infection or vaginal trauma is present.
- DO NOT USE AFTER EXPIRATION DATE.

Learn more at mybabydance.com or (800) 367-2837.

Made in the USA for Fairhaven Health, LLC
1410 11th Street
Bellingham, WA 98225

United States Patent No. 9,913,871

Part #: BD300-3