

BabyDance®

Fertility Lubricant

Instructions

Package Contents

1 multiuse tube (40 gm/1.4 oz.) with 10 single-use applicators

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 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 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. For first use, remove the tube cap and puncture the protective seal with the cap point.
2. Unwrap one applicator. With the applicator plunger closed, twist the applicator onto the tube of BabyDance.
3. Squeeze approximately 3 grams of BabyDance into the applicator.
4. BabyDance should be used **immediately** once the applicator is filled. Holding the applicator with the open end up, untwist the applicator from the 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 toward 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 into the vagina, depress the plunger to deliver BabyDance. Then remove the applicator and discard it.

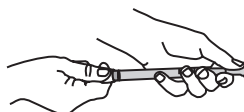
To apply BabyDance externally, squeeze a generous amount into your hand and apply to the vulvar area and/or your partner's penis. Reapply as needed.

Using BabyDance With Condoms

To use with nonlubricated or polyurethane condoms, squeeze BabyDance into your hand and apply to the outer condom surface. 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.

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	2,000 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. Applicators are intended for single use only. DO NOT REUSE applicators. Store at 36-86 °F (2-30 °C). Close cap tightly between each use.

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

Learn more at fairhavenhealth.com or 800.367.2837.

Made in the USA for Fairhaven Health, LLC
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Part #: FH.BABYDANCE40GAPP-I.REV02


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Final Audit Report

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